NOTE: Appendix 2 of this guidance has been superseded by **Attachment 1. List of SUDS Known to be Reprocessed or Considered for Reprocessing** at Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data.

Guidance for Industry and FDA Reviewers

Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme

Draft Guidance – Not for Implementation

This guidance document is being distributed for comment purposes only.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation

Preface

Public Comment:

Comments and suggestions regarding this document should be submitted by April 11, 2000 to Docket No. 00D-0053, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, (HFA-305), Room 1061, Rockville, MD 20852.

Additional Copies:

World Wide Web/CDRH home page at http://www.fda.gov/cdrh/reuse/1156.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1156 when prompted for the document shelf number.

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Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme[1]

Introduction

The practice of reprocessing devices that are intended for single-use (SUD's) began in hospitals in the late 1970's. Since that time, the practice of reprocessing and reusing SUDs has become widespread. FDA has not regulated original equipment manufacturers (OEM's), third parties, and hospitals that engage in reprocessing SUD's in the same manner. In particular, to date, FDA has enforced existing premarket submission requirements only against OEM's. FDA's premarket review of an OEM's device labeled for single-use does not ordinarily address whether reprocessing and reuse of such a device would present a risk to the public health.

The public health risk presented by a reprocessed SUD varies. Some devices, which are low risk when used only one time, may present an increased risk to the patient upon reprocessing. Other SUDs are low risk when used for the first time and remain low risk after reprocessing, provided that the reprocessor conducts cleaning and sterilization/disinfection of the SUD in an appropriate manner. Other SUDs, however, cannot be reprocessed safely and should not be reprocessed and reused under any circumstances. FDA is proposing to prioritize its enforcement of premarket requirements for reprocessed SUDs on the basis of the risk that is likely to be posed by the reuse of the device. This guidance document describes the factors the agency will consider to determine the level of risk associated with these devices and the way those factors will be applied to determine whether the risk is high, moderate, or low.

[1] This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations or both.

Purpose

This document describes the process FDA would use to categorize the risk of SUDs that are reprocessed. The process, called the Review Prioritization Scheme (RPS), assigns risk categories to frequently reprocessed SUDs. The process itself is illustrated through flow charts in Appendix 1 and the risk categories assigned through the process to frequently reprocessed SUDs are listed in Appendix 2.

FDA anticipates using the RPS in the future in response to requests from the public on the category of a reprocessed SUD not listed in Appendix 2. Such requests should be directed, in writing, to the contact noted in the Preface. FDA will periodically publish a revised list of categorized devices based upon these requests.

The RPS assigns an overall risk to each SUD by addressing the risk of infection and the risk of inadequate performance following reprocessing. The FDA intends to utilize the overall risk level to prioritize the enforcement of premarket submissions for these devices. Enforcement priorities for reprocessed SUDs are further described in the companion draft guidance entitled: "Enforcement Priorities for Single-Use Devices Reprocessed by Third-Parties and Hospitals." FDA wants to clarify that neither of these guidance documents change the classification of devices under section 513 of the Federal Food, Drug, and Cosmetic Act or establish some system of classification outside that statutory process. The risk prioritization scheme is intended to help FDA and stakeholders determine the level of risk associated with the reuse of single use devices and the enforcement strategy guidance presents FDA's current thinking on the time table it will use to phase in the enforcement of regulatory requirements for third parties and hospitals that may intend to reprocess these products.

FDA is seeking input from users, original equipment manufacturers (OEMs), reprocessors, and the general public about this proposed approach for categorizing risk. The attached list in Appendix 2 of this draft RPS guidance identifies frequently reprocessed SUD's and their risk categorization. We acknowledge that this list may be incomplete or that the grouping of devices based on current classification regulations may be too broad. FDA will consider any SUD not on the current list or subsequently revised lists to be one that poses a high risk if it is reprocessed. FDA is soliciting public

comment on the list and may revise the factors to categorize risk and the category of risk assigned to specific devices based upon the comments. After receiving comments on this draft guidance, FDA will issue a final guidance. On December 10, 1999 FDA published an earlier version of this draft document on its Website and recently issued a Federal Register notice announcing the availability of the that earlier version. This draft guidance replaces the earlier version in its entirety.

Scope

This draft RPS guidance **IS** applicable to third party and hospital reprocessors of SUDs.

This draft guidance **DOES NOT** apply to:

1. Permanently implantable pacemakers. Questions regarding the reuse of permanent pacemakers are addressed in Compliance Policy Guide 7124.12 (issued on October 1, 1980 and revised in March 1995).

2. "Opened-but-unused" SUDs (as defined in Appendix A of the companion guidance: "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals").

3. Health care facilities that are not hospitals[2].

FDA is aware that hospitals may not be the only health care facilities that reprocess devices labeled for single use. At this time, the agency is limiting its focus to SUD reprocessing by third party and hospital reprocessors. In the near future, FDA intends to examine whether it should include other establishments that may reprocess SUDs.

[2] For the purpose of this draft guidance, a hospital is defined as an acute health care facility.

General Approach

The RPS identifies two types of risks that arise as a result of using a reprocessed SUD: (1) the risk of infection; and (2) the risk of inadequate or unacceptable device performance following reprocessing. Based on the risk of infection and inadequate device performance, the scheme places SUDs in overall risk categories of low, moderate, or high. As noted above, these risk categories will be used in establishing FDA's enforcement priorities and periods of enforcement discretion for premarket requirements.

The worksheet and flowcharts attached (Appendix 1) to this guidance are the tools that FDA has used when applying the RPS. It is important to note that many of the questions asked in the flowcharts may require subjective responses. Despite the possibility of different interpretations, FDA has tried to make consistent categorizations across all SUD types.

Flowchart 1: Evaluating the Risk of Infection (Appendix 1)

One of the FDA's primary concerns is the risk of disease transmission during reuse of a reprocessed SUD. For a reusable device, the OEM provides the user with validated step-by-step reprocessing instructions or the methods to reprocess for reuse are commonly known and accepted. However, the OEM of a single-use device does not consider safety and effectiveness issues related to reprocessing the device for reuse. Flowchart 1 evaluates the risk of infection posed by reuse of a SUD following reprocessing.

FDA considers all implantable SUDs to be high risk. Implantable devices are defined in 21 CFR Part 860.3(d). Flowchart 1 pertains only to non-implantable devices.

Question 1: Is the SUD a non-critical device?

The chart asks how the device will contact the patient, or in some cases, the user or health care worker, by applying the definitions of the Spaulding criteria[3] for critical, semi-critical, and non-critical devices.

[3] Spaulding, E.H. 1972. Chemical disinfection and antisepsis in the hospital. J. Hosp. Res., 9, 5-31.

A non-critical device is a device that is intended to make topical contact and not penetrate intact skin. A non-critical device presents a low risk of disease transmission when reprocessed and reused.

A semi-critical device is a device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body. A semi-critical device presents a greater risk of disease transmission than a non-critical device.

A critical device is a device that is intended to contact normally sterile tissue or body spaces during use and presents the greatest risk of disease transmission.

If the answer to question 1 is "Yes", then the risk of infection is low.

If "No", go to question 2.

<u>Question 2</u>: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of a SUD that has not been reprocessed?

If the device were determined to be critical or semi-critical, FDA would evaluate existing postmarket data (e.g., published data, laboratory reports, reports to FDA) to determine if the reprocessed SUD may present an increased risk of infection when compared to the use of a SUD that has not been reprocessed. FDA believes that the existence of significant adverse postmarket data is a compelling reason for concern and, therefore, FDA would consider the device to be high risk.

If the answer to question 2 is "Yes", then the risk of infection is high.

If "No", go to question 3.

<u>Question 3</u>: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?

Some design features, such as narrow lumens and interlocking parts, can harbor debris that cannot be readily accessed and removed during cleaning unless the device can be disassembled or otherwise serviced and all surfaces of the devices exposed for manual cleaning. If a device cannot be adequately cleaned, terminal processing to disinfect or sterilize the device will not be successful and the SUD presents a greater risk of disease transmission. If a device does not incorporate any of these hard to clean features, then the SUD presents a low risk of disease transmission.

If the answer to question 3 is "Yes", then go to question 4.

If "No", then the risk of infection is low.

<u>Question 4</u>: Does a reusable device exist that has an equivalent design and the same intended use as the SUD?

In some circumstances, there will be cleared, approved, or exempt reusable devices (including designs with problematic construction or materials features) that are equivalent to a SUD with the same intended use. In this case, the risk is diminished because it is evident that cleaning and sterilization/disinfection can be accomplished with the reprocessed SUD by using techniques directed by labeling for the reusable device.

If the answer to question 4 is "Yes," then the risk of infection is low.

If "No," then go to question 5.

<u>Question 5</u>: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the SUD has been adequately cleaned and sterilized/disinfected?

FDA has recognized numerous domestic and international consensus standards that may be used for design and performance aspects of the

reprocessed SUD. The list of FDA-recognized standards is available on FDA's website www.fda.gov/cdrh/modact/recstand.html. OEM-recommended performance tests (e.g., manufacturer-developed test, standards that are not recognized) may also be applicable. In addition, there are CDRH guidance documents on FDA's website www.fda.gov/cdrh/guidance.html, which may include specifications, test protocols, and acceptance criteria.

If the answer to question 5 is "Yes", then the risk of infection is moderate.

If "No", then go to question 6.

Question 6: Is this a semi-critical device?

If the SUD is a semi-critical device, the risk of infection is moderate.

However, if a product is a critical device, the risk of infection is high.

Flowchart 2: Risk of Inadequate Performance (Appendix 1)

Another one of FDA's primary concerns is the risk of inadequate performance during reuse of a reprocessed SUD. For a reusable device, the OEM validates that the device will perform without failure for the number of times it is labeled to be reused. However, a manufacturer of a SUD validates that the SUD will perform without failure for only one use. In Flowchart 2, we evaluate the risk of inadequate performance posed by reuse of a SUD following use and reprocessing.

FDA considers all implantable SUDs to be high risk. Implantable devices are defined in 21 CFR Part 860.3(d). Flowchart 2 pertains only to non-implantable devices.

<u>Question 1</u>: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?

FDA evaluates existing postmarket data (e.g., published data, laboratory reports, reports to FDA) to determine if the reprocessed SUD may present an increased risk of injury when compared to the use of a SUD that has not been reprocessed. FDA believes that existence of significant adverse postmarket data is a compelling reason for concern and, therefore, would consider the device to be high risk. FDA does not consider the absence of relevant information to be either evidence of increased risk or proof of safety.

If the answer to question 1 is "Yes", then the risk of inadequate performance is high.

If "No", go to question 2.

<u>Question 2</u>: Could failure of the device cause death, serious injury, or permanent impairment?

For purposes of risk categorization associated with inadequate performance, Flowchart 2 distinguishes between those SUDs whose failure could cause death, serious injury, or permanent impairment and those SUDs whose failure would cause less severe harm.

If the answer to question 2 is "Yes", then go to question 3.

If "No", go to question 2a.

<u>Question 2a</u>: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?

FDA has recognized numerous domestic and international standards that may be used for design and performance aspects of the reprocessed SUD. The list of FDA-recognized standards is available on FDA's WEBsite. OEM-recommended performance tests (e.g., manufacturer-developed tests, standards that are not recognized) may

also be applicable. In addition, there are CDRH guidance documents on FDA's WEBsite, which may include specifications, test protocols, and acceptance criteria.

If the answer to question 2a is "Yes", then the risk of inadequate performance is low.

If "No", then go to question 2b.

<u>Question 2b</u>: Can visual inspection determine if performance has been affected?

Visual, critical failure of the device may be self-evident before or during use of the device. Measures can then be implemented to correct the failure.

If the answer to question 2b is "Yes" then the risk of inadequate performance is low.

If "No", then the risk of inadequate performance is moderate.

<u>Question 3</u>: Does the SUD contain any materials, coatings, or components that may be damaged or altered by a single use or by reprocessing and/or resterilization/disinfection in such a way that the performance of the device may be adversely affected?

Materials, coatings, or components may be damaged or altered by a single use or by reprocessing. For example, battery life, material strength or flexibility, lubrication, and antimicrobial coatings may be adversely affected.

If the answer to question 3 is "Yes" then go to question 4.

If "No" then go back to question 2a.

<u>Question 4</u>: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?

FDA has recognized numerous domestic and international standards that may be used for design and performance aspects of the reprocessed SUD. The list of FDA-recognized standards is available on FDA's WEBsite. OEM-recommended performance tests (e.g., manufacturer-developed tests, standards that are not recognized) may also be applicable. In addition, there are CDRH guidance documents on FDA's WEBsite, which may include specifications, test protocols, and acceptance criteria.

If the answer to question 4 is "Yes", then the risk of inadequate performance is moderate.

If "No", then go to question 5.

<u>Question 5</u>: Can visual inspection determine if performance has been affected?

Visual, critical failure of the device may be self-evident before or during use of the device. Measures can then be implemented to correct the failure

If the answer to question 5 is "Yes," then the risk of inadequate performance is moderate.

If "No," then the risk of inadequate performance is high.

How to Determine the Risk of a Reprocessed and Reused SUD

After determining the risk of infection from Flowchart 1 and the risk of inadequate performance from Flowchart 2, the worksheet in Appendix 1 is used to determine the overall risk presented by reprocessing the SUD. Step-by-step instructions for using the worksheet follow:

1. As noted in the introduction to each flowchart, if the device is an implant, as defined in 21 CFR Part 860.3(d), the SUD is categorized as high risk and no further evaluation is necessary.

2. Determine the risk of infection posed by reprocessing and reuse of a SUD using Flowchart 1. Based upon this flowchart, the risk of infection will be low, moderate, or high. If the risk of infection is high, the overall risk is also considered high and no further evaluation is necessary.

3. Determine the risk of inadequate performance of a reprocessed and reused SUD using Flowchart 2. Based upon this flowchart, the risk of inadequate performance will be low, moderate, or high. If the risk of inadequate performance is high, the overall risk is also considered high and no further evaluation is necessary.

4. If the SUD was assigned a moderate risk for either Flowchart 1 or Flowchart 2, then the overall risk is also considered to be moderate.

5. If a SUD was assigned a low risk for both Flowchart 1 and Flowchart 2, then the overall risk associated with reprocessing is considered to be low.

Applying the RPS: Examples

FDA is providing 3 examples of how the RPS can be used to assess the overall risk of a reprocessed SUD. The headings for the examples note the risk category, the generic type of device, and, in parentheses, the FDA classification regulation number and internal three-letter product codes assigned by FDA. The questions in the examples are paraphrased from the flowcharts.

Example 1

Example 1: Low Risk SUD: Orthopedic Drill Bit (878.4540 HTW)

Evaluation of infection risk: Flowchart 1

Question 1: Is the orthopedic drill bit a non-critical device?

The answer to Question 1 is "No" because the drill bit makes contact with a normally sterile area.

Go to Question 2.

Question 2: Does FDA have postmarket data that suggest using a reprocessed drill may present an increased risk of infection?

At this time, the FDA does not know of any postmarket data that suggest using a reprocessed drill bit may present an increased risk of infection when compared to the use of a drill bit that has not been reprocessed.

The answer to Question 2 is "No."

Go to Question 3.

Question 3: Does an orthopedic drill bit have features that may impede cleaning and disinfection or sterilization?

The answer to Question 3 is "No."

Therefore, the drill bit presents a Low Risk of infection.

Example 1

Evaluation of risk of inadequate performance: Flowchart 2

Question 1: Does FDA have postmarket data that suggest using a reprocessed drill may present increased risk of performance failure?

At this time, FDA does not know of any postmarket data that suggest a orthopedic drill bit may present an increased risk of performance failure compared to the use of a drill bit that has not been reprocessed and reused.

The answer to Question 1 is "No."

Go to Question 2.

Question 2: Will failure of an orthopedic drill bit cause death, serious injury, or permanent impairment?

The answer to Question 2 is "No."

Go to Question 2a.

Question 2a: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance that may be used to determine if the performance of the drill bit has been altered due to reprocessing and use?

The answer to question 2a is "No".

Go to Question 2b.

Example 1

<u>Question 2b</u>: Can adequate performance of all vital parameters related to safety and effectiveness be determined by visual inspection of the drill bit?

The answer to Question 2b is "Yes".

Therefore, an orthopedic drill bit has a low risk of inadequate performance

Worksheet Results

1. An orthopedic drill bit is not an implant.

2. The risk of infection according to Flowchart 1 is Low Risk.

3. The risk of inadequate performance according to Flowchart 2 is Low Risk.

4. The orthopedic drill bit resulted in Low Risk on both flow charts; therefore the device is **Low Risk**.

Example 2

Example 2: Moderate Risk: Operating Room Drapes (878.4370 KKX)

Evaluating infection risk: Flowchart 1

Question 1: Is an operating room drape a non-critical device?

The answer to this question is "No" because an operating room drape may come in contact with mucous membranes as well as normally sterile body tissues.

Go to Question 2.

Question 2: Does FDA know about any postmarket data that suggest that there is an increased risk of infection?

At this time, FDA does not know of any postmarket data on drapes that suggest using the reprocessed drape may present an increased risk of infection when compared to the use of a drape that has not been reprocessed.

The answer to Question 2 is "No."

Go to Question 3.

Question 3: Does the OR drape have any features that could impede thorough cleaning and adequate sterilization?

The answer to Question 3 is "No."

Therefore, a single-use only OR drape is considered a Low Risk device for infection when reprocessed and reused.

Example 2

Evaluation of risk of inadequate performance: Flowchart 2

Question 1: Does postmarket information suggest there is an increased risk of injury?

At this time, the FDA does not know of any postmarket data that suggest that the reprocessed drape may present an increased risk of patient injury when compared to the use of a drape that has not been reprocessed.

The answer to Question 1 is "No."

Go to Question 2.

Question 2: Could failure of the OR drape cause death, serious injury, or permanent impairment of the patient?

If the drape fails as a barrier device, it may allow transmission of disease.

The answer to Question 2 is "Yes."

Go to Question 3.

Question 3: Does the SUD contain materials that may be damaged or altered by a single use?

Some OR drapes contain materials, coating or components that may be damaged or altered by either a single-use or by reprocessing in such a way that the drape performance may be affected.

The answer to Question 3 is "Yes."

Go to Question 4.

Example 2

<u>Question 4</u>: Are there recognized standards that may be used to determine if performance has been altered?

The following two standards are available for testing the barrier properties of drapes: ASTM F1671-97b "Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage as a test system;" and ASTM F1670-97 "Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood."

The answer to Question 4 is "Yes."

Therefore, the OR drape presents a Moderate Risk of inadequate performance.

Worksheet Results

1. An OR drape is not an implant

2. The risk of infection according to Flowchart 1 is Low Risk.

3. The risk of inadequate performance according to Flowchart 2 is Moderate Risk.

4. The OR drape resulted in a Moderate Risk on Flowchart 2; therefore, the device is **Moderate Risk**.

Example 3

Example 3: High Risk: Cardiac Ablation Catheter (unclassified, LPB)

Evaluating infection risk: Flowchart 1

<u>Question 1</u>: Is the SUD a noncritical device?

Cardiac Ablation Catheters are introduced directly into the bloodstream. Therefore, they are considered critical devices.

The answer to Question 1 is "No."

Go to Question 2.

<u>Question 2</u>: Does postmarket information suggest that there is an increased risk of infection?

At this time, FDA does not know of any postmarket data on cardiac ablation catheters that suggest that using the reprocessed catheter may present an increased risk of infection when compared to the use of a cardiac ablation catheter that has not been reprocessed and/or reused.

The answer to Question 2 is "No."

Go to Question 3.

<u>Question 3</u>: Does the SUD include features that impede thorough cleaning and sterilization/disinfection?

Cardiac ablation catheters do have features that could impede thorough cleaning and adequate sterilization (e.g.,. band electrodes).

The answer to Question 3 is "Yes."

Go to Question 4.

Example 3

<u>Question 4</u>: Does a reusable device exist that has an equivalent design and the same intended use?

At this time FDA does not know of any reusable catheter that has an equivalent design (including materials) and the same intended use (including anatomical site of use) as a cardiac ablation catheter.

The answer to Question 4 is "No."

Go to Question 5.

<u>Question 5</u>: Are there recognized standards that may be used to determine if the SUD has been adequately cleaned and sterilized/disinfected?

At this time there are no recognized standards, tests recommended by the OEM, or a CDRH guidance that may be used to determine if the cardiac ablation catheter has been adequately cleaned and disinfected/sterilized.

The answer to Question 5 is "No."

Go to Question 6.

<u>Question 6</u>: Is this a semi-critical device?

No, cardiac ablation catheters are critical devices.

Therefore, cardiac ablation catheters are considered to pose a high risk of infection if reprocessed and reused.

Example 3

Evaluation of risk of inadequate performance: Flowchart 2

Question 1: Does postmarket information suggest there is an increased risk of injury?

Significant postmarket data (published literature) exists that suggest that the reprocessed cardiac ablation catheter may present an increased risk of patient injury.

The answer to Question 1 is "Yes."

Therefore, cardiac ablation catheters are considered to have a high risk of inadequate performance if reprocessed and reused.

Worksheet Results

1. Cardiac ablation catheters are not implants.
2. The risk of infection according to Flowchart 1 is High Risk.
3. The risk of inadequate performance according to Flowchart 2 is High Risk.
4. The cardiac ablation catheter resulted in a High Risk on Flowcharts 1 and/or 2; therefore, the device is **High Risk**.

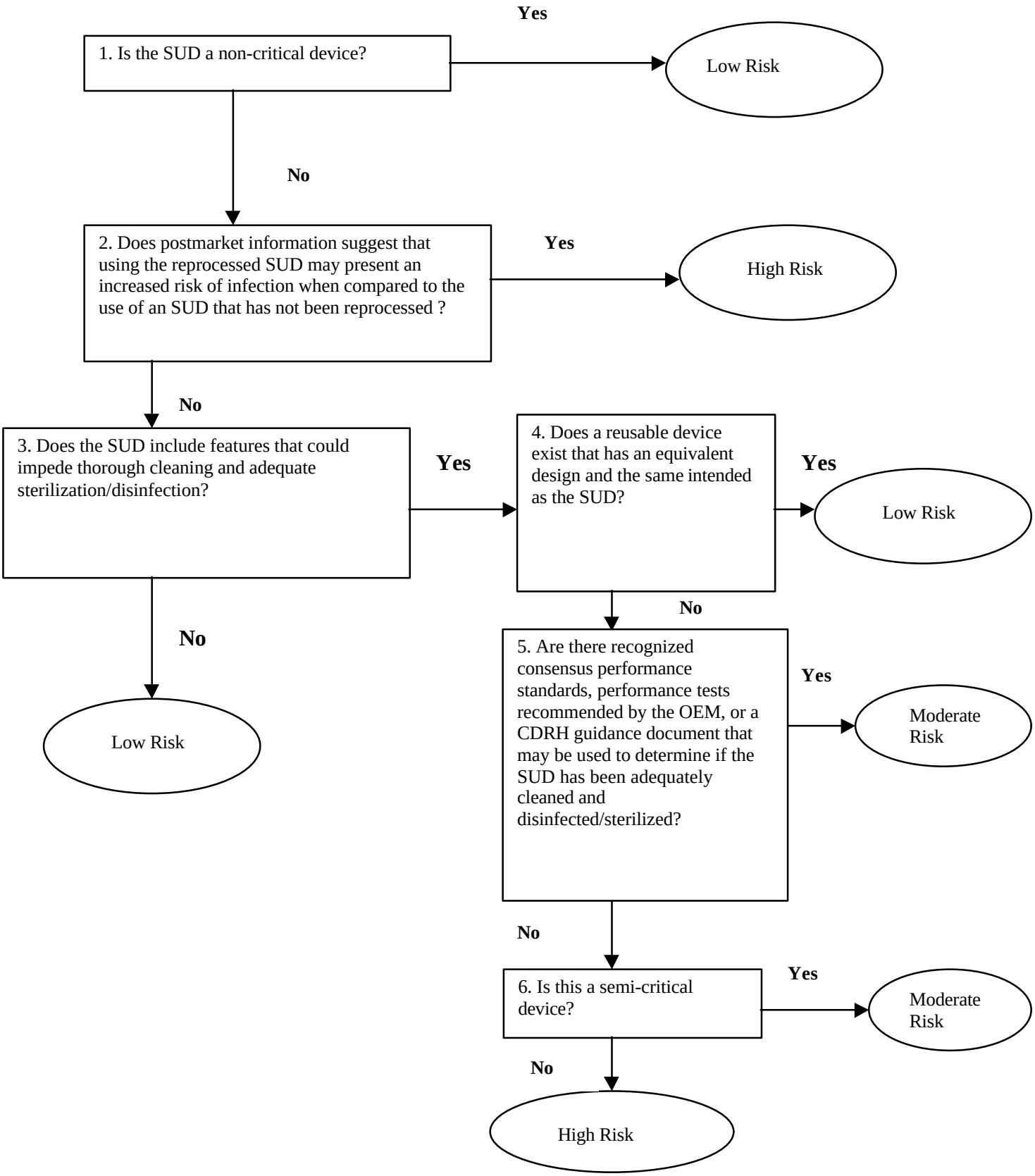
List of Frequently Reprocessed SUDs

Appendix 2 is a list of frequently reprocessed devices identified by FDA and categorized by risk. The list includes:

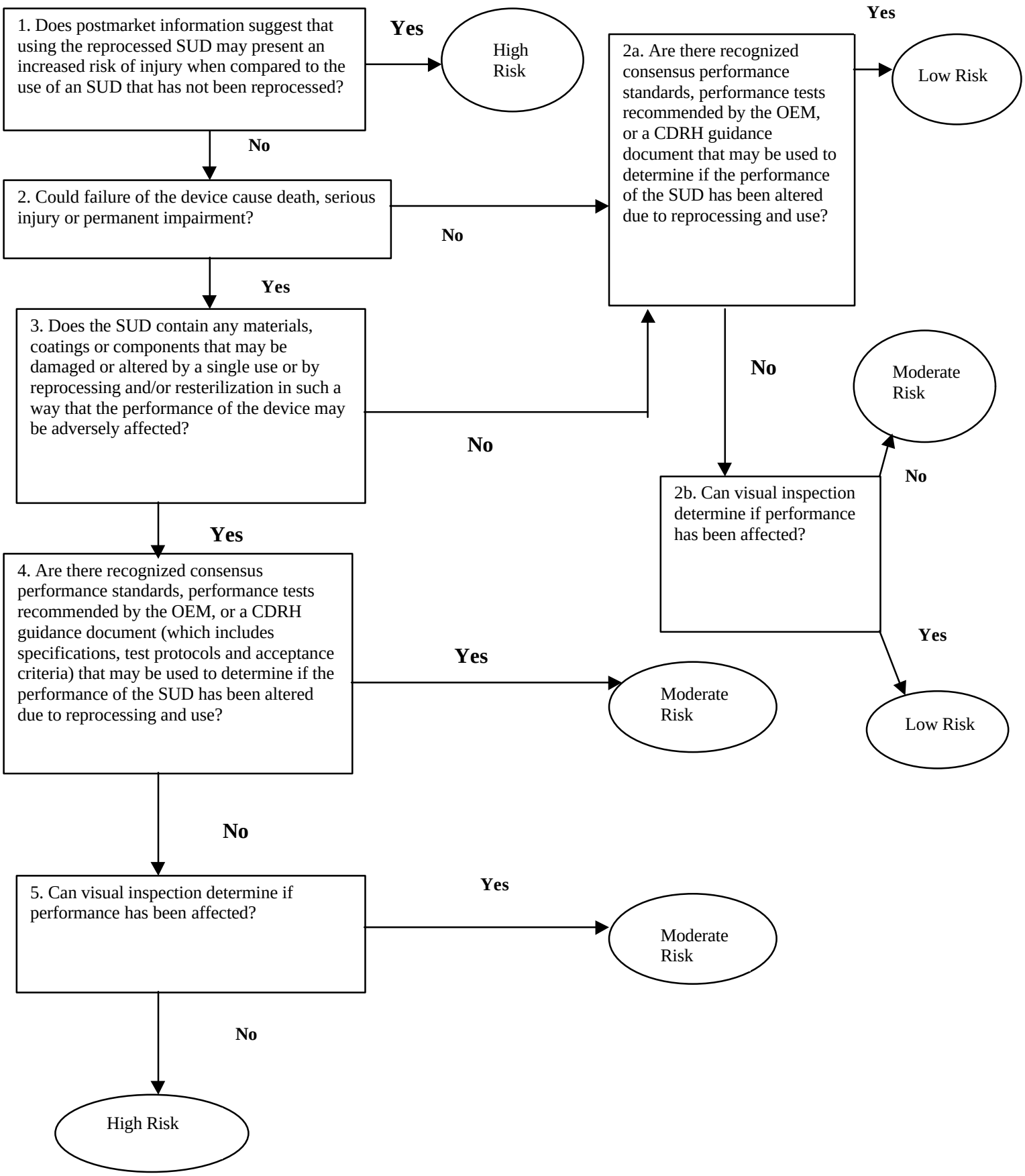
- the general medical specialty area,
- the generic name of the device,
- the classification regulation related to the generic type of device (see 21 Code of Federal Regulations),
- whether the generic type of device is exempt from premarket notification by regulation,
- the type of premarket submission that may be required for the device,
- the regulatory class of the device,
- the internal FDA procodes for the device, and
- the risk category under the RPS.

Appendix 1

Flowchart 1 – Infection Risk



Flowchart 2 – Inadequate Performance Risk



Work Sheet

1. **Is the SUD an implant as defined in 21 CFR Part 860.3(d)?**

   Yes or NO

   If the answer to question #1 above is Yes, STOP. SUD is categorized as High Risk.

2. **What is the risk of infection according to Flowchart 1?**

   Low Risk or Moderate Risk or High Risk

   If the answer to question #2 is High Risk, STOP. SUD is categorized as High Risk.

3. **What is the risk of inadequate performance according to Flowchart 2?**

   Low Risk or Moderate Risk or High Risk

   If the answer to question #3 is High Risk, STOP. SUD is categorized as High Risk.

4. **Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.**

5. **Did the SUD result in a Low Risk on Flowcharts 1 AND 2? If so, the SUD is low risk.**

Please circle appropriate risk categorization below.

Low Risk or Moderate Risk or High Risk

Appendix 2

List of Frequently Reprocessed SUDs

Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Cardiovascular	Angiography catheter	870.1200	N	510(k)	II	DQO	high
	blood pressure cuff	870.1120	N	510(k)	II	DXQ	low
	cardiac ablation catheter	unclassified	N	PMA	III	LPB	high
	cardiac guidewire	870.1330	N	510(k)	II	DQX	high
	compressible limb sleeve	870.5800	N	510(k)	II	JOW	low
	Electrophysiology recording catheter	870.1120	N	510(k)	II	DRF	high
	intra aortic balloon catheter	870.3535	N	510(k)	III	DSP	high
	needle	870.1390	N	510(k)	II	DRC	high
	percutaneous transluminal coronary angioplasty (PTCA) catheter	unclassified	N	PMA	III	LOX	high
	percutaneous transluminal angioplasty (PTA) catheter	unclassified	N	510(k)	II	LIT	high
	syringes	870.1670, 870.1650, unclassified	N	510(k)	II	DXT	high
	trocar	870.1390	N	510(k)	II	DRC	moderate
Respiratory	breathing mouthpiece	868.5620	Y	N/A	I	BYP	low
	endotracheal tubes	unclassified	N	PMA	III	LZN	high
	masks	868.5550	Y	N/A	I	BSJ	low
	oral and nasal catheters	868.5350	Y	N/A	I	BZB	low
	respiratory therapy and anesthesia breathing circuits	868.5240	Y	N/A	I	CAI	moderate
	tracheobronchial suction catheter	868.6810	N	510(k)	I	BSY	high

Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Gastroenterology/ Urology	biliary sphincterotomes	876.4300	N	510(k)	II	KNS	high
	biopsy needles	876.1075	N	510(k)	II	FCG	high
	endoscopic guidewires	876.1500	N	510(k)	II	KOG	low
	endoscopic staplers	876.4400	N	510(k)	II	FHN	low
	extraction balloons/baskets	876.1500	N	510(k)	II	KOG	high
	non-electric biopsy forceps	876.1075	N	510(k)	II	FCL	high
	trocar	876.5090	N	510(k)	II	FBQ	low
	urethral catheters	876.5130	N	510(k)	II	KOD	moderate
Nephrology	hemodialysis blood tubing	876.5820	N	510(k)	II	KOC	moderate
OB-GYN	laparoscopic dissectors	884.1720	Y	N/A	I	HET	low
	laparoscopic graspers	884.1720	Y	N/A	I	HET	high
	laparoscopic scissors	8884.1720	Y	N/A	I	HET	high
	trocar	884.1720	N	510(k)	II	HET	low
Orthopedics	arthroscopy instruments	888.1100	N	510(k)	II	HRX	low
	carpal tunnel blade	888.4540	Y	N/A	I	LXH	moderate
	drill bits	878.4540	Y	N/A	I	HTW	low
	external fixation device	878.3900, 878.3910	Y	N/A	I	FZF, FYH	low
	flexible reamers/drills	886.4070 878.4820	Y	N/A	I	GEY, HRG	low
	saw blades	878.4820	Y	N/A	I	GFA, DWH, GEY, GET	low
	surgical drills	878.4820	Y	N/A	I	GEY, GET	low
Surgery	biopsy forceps	876.1075 876.4300 884.4530 874.4680 874.4680	N	510(k)	II	FCL KGE HFB BWH JKK	high
	biopsy needles	878.4800	Y	N/A	I	DWE	high
	burr	878.4820	Y	N/A	I	GFF, GEY	low

Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
	electrosurgical electrodes/handles/ pencils	876.4300 878.4800	N	510(k)	II	HAM, GEI, FAS, FEH, KNS	moderate
	endoscopes	876.1500	N	510(k)	II	many	high
	endoscopic blades	876.1500	N	510(k)	II	GCP, GCR	moderate
	endoscopic guidewires	876.1500	N	510(k)	II	GCP, GCR	low
	enodoscopic staplers	888.4540	Y	N/A	I	HXJ	moderate
	fascia holders	878.4800	Y	N/A	I		moderate
	laproscope	884.1720 876.1500	N	510(k)	II	HET, GCJ	low
	laser fiber delivery systems	878.4810 874.4500 874.4770 874.4496 878.4810 886.4390 884.4550 886.4690	N	510(k)	II	GEX, EWG, LXR, LMS, LLW, HQF, HHR, HQB,	low
	scissor tips, removable inserts	878.4800 888.4540 884.4520 874.4420	Y	N/A	I	LRW, HHR, HDK, HDJ, JZB, KBD	moderate
	surgical cutting accessories	878.4800 874.4420	Y	N/A	I	GDZ, GDX, GES, KBQ, KAS	moderate
	trocar	874.4420 876.5090 876.1500 870.1390	Y	N/A	I	KAB KBG KCI	moderate
	trocar	874.4420 876.5090 876.1500 870.1390	N	510(k)	II	FBQ, FBM, GCJ, DRC	moderate

Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Plastic Surgery	stapler	878.4800 882.4190	Y	N/A	I	GAG, GEF, FHM, HBT, HBS	moderate
Laboratory	glucometer lancets	878.4800	Y	N/A	I	FMK	low
Ophthalmic	keratome blade	886.4370	N	510(k)	I	HMY, HNO, MYD	high
	OR drapes	878.4370	N	510(k)	II	KKX	moderate
	phacoemulsification needle	886.4670	N	510(k)	II	MUS	high
Infection Control	OR gowns	878.4040	N	510(k)	II	FYA	low
	sharps containers	880.5570	N	510(k)	II	MTV, FMI	low
	syringes, piston	880.5860	N	510(k)	II	FMF	high
General Hospital	infusion pump, implanted	unclassified	N	PMA	III	MDY, LKK	high
	syringe, irrigating	880.6960	Y	N/A	I	KYZ, KYY	low
Dental	braces, plastic	872.5470	N	510(k)	II	DYW	high
	braces, metal	872.5410	Y	N/A	I	EJF	high
	burr	872.3240	Y	N/A	I	EJL	moderate