ETHICON ENDO-SURGERY, INC.
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January 17, 2003

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0456
Medical Device User Fee and Modernization Act of 2002, Title III, Sec. 302 (b) (o) (1) (A),(B),(C),(D) and (2)(A)

To Whom It May Concern:

Per the Medical Device User Fee and Modernization Act of 2002 (MDUFA), this letter provides a list of device types that Ethicon Endo-Surgery, Inc. (EES) believes should undergo full validation testing if these devices are reprocessed and commercialized by another manufacturer. Results of this testing should be submitted in a new 510(k) by the reprocessor. Validation is needed to ensure that the reprocessed devices are safe and effective and do not put subjects at increased risk.

The recommended list of devices subject to validation is derived from two sources: (1) safety complaints involving reprocessed Harmonic Scalpel blades and (2) actual testing of a wide range of reprocessed devices picked up in the field.

Safety Complaints involving Harmonic Scalpel Blades

Pertaining to safety complaints involving the Harmonic Scalpel blades, Ethicon Endo-Surgery, Inc. modified five UltraCision Harmonic Scalpel blades (K010898) by adding a protective sleeve, based on information that practitioners might be using the device in an off-label manner, such as resterilizing these single use blades.

The modification was undertaken because when these blades, which are labeled as single use products, are resterilized contrary to the labeling instructions, the center of the blade sheath exhibits elevated temperatures. This area can be a point of contact between the device and the patient if the blade sheath is resting against the patient. The practice of reprocessing traps liquid between the blade and the blade sheath and when the device is activated for long durations, this liquid causes the sheath temperatures to go beyond acceptable ranges in the clinical setting. There have been occurrences of patients with thermal injury resulting from the inappropriate sterilization of these single use devices.

The protective sleeve provides a thermal barrier between the blade sheath and the patient. The protective sleeve is an added measure to mitigate the risk of thermal injury even further. Unfortunately, not every device can or should be redesigned because of potential reprocessing.

Testing of Reprocessed Devices

Regarding actual testing of a wide range of reprocessed devices picked up in the field, data in four recent studies were used: (1) a study by McCrone Associates, Inc. in Westmont, Illinois entitled "Microscopical Examination of Reprocessed Surgical Instruments" dated November 8, 2002, sponsored by Ethicon Endo-Surgery, Inc., (2) an internal study by Ethicon Endo-Surgery, Inc. dated April 4, 2000 entitled "Evaluation of Reprocessed Single Patient Use (SPU) Devices," (3) an internal study by Ethicon Endo-Surgery, Inc. dated October, 1999 entitled "Evaluation of Reprocessed Single Patient Use (SPU) Devices," and (4) a report published by The Association of Disposable Device Manufacturers dated April 27, 1999 entitled "Evaluation of Safety and Performance of Reprocessed Single-Use Medical Devices, Experience of Three Medical Device Manufacturers: Ethicon Endo-Surgery, Inc., Boston Scientific Corporation, U. S. Surgical Corporation." Copies of these reports are attached.

A total of 222 devices were tested in the four studies on single patient use devices for the purpose of conducting engineering analyses and to observe the effects of reprocessing and reuse. All devices were received unopened in the reprocessor's packaging. The testing activities were: 1) visual inspection of the device in the package, 2) microscopic inspection of the device and package after removal of the device from the package, 3) performance testing to manufacturing quality standards and 4) device disassembly and examination by microscope. In some cases testing for sterility was also performed.

The results from this testing indicate that the practice of reprocessing single patient use devices degrades product quality and sometimes sterility.

Explanation of the Table

The following table contains specific examples of types of devices and specific hazards after reprocessing these devices (documented in the four studies mentioned above) for which validation should be required. The 21CFR reference and listed FDA Pro Code as well as the 510(k) associated with each device is listed. General findings and/or observations noted in the study are mentioned along with the potential hazards as a result of reprocessing. Each type of hazard is described in detail following the table. The studies used as the basis for this table are mentioned following the hazard descriptions. Because of the preponderance of data, only certain devices from these four recent studies have been included.

Table of Specific Risks for Specific Devices Requiring Validation

Based on actual testing of a wide range of reprocessed devices mentioned in four studies/evaluations of safety and performance of reprocessed single-use medical devices**

21 CFR # / Name					Potential Hazards after Reprocessing * (see description of each category below)					
Listed FDA Pro Code	Device Type	510(k)	Findings / Observations	Report	Sterility	Energy	Biological	Environ-mental	Use	Functional
876.1500 Endoscope & Accessories										
GCJ	Trocar	K952842	Stopcock broken off	EES		X			X	X
KOG	Linear Cutter	K002398	Material and possibly blood on anvil, rust corrosion on handle and trigger mechanism	McC	X	X	X	X	X	X
FHO	Needle - Pneumoperitonium	K910875	Mislabeled	ADDM					X	
FHP	Needle - Veress	K983925	Mislabeled and missing packaging label	ADDM					X	
884.1720 Laparoscope, Gynecologic & Accessories										
HET	Trocar	K914968	Packaging torn; seal damaged	EES	X		X			
HET	Trocar	K914968	Crack at housing / cannula joint	EES		X			X	X
878.4400 Electrosurgical Cutting & Coagulation Device & Accessories										
GEI	Electro. Scissors	K910831	Not sterile and failure to open/close properly	ADDM	X	X	X		X	X
GEI	Electro. Scissors	K910831	Shaft bowed; dull and bent scissors; scissors failed to cut test material	EES		X			X	X
GEI	Electro. Scissors	K984240	Nicks and scratches in the sheath	McC		X			X	X
GEI	Electro. Shears	K925699	Blemished and improperly sharpened blade; damaged tooth profile; torn clamp pad; rough alignment pin	ADDM		X			X	X
GEI	Electro. Shears	K925699	Showed wear on coated metallic sheath; particle on clamp pad on the jaw	EES		X	X		X	X
GEI	Electro. Shears	K925699	4 out of 5 devices tested required actuation forces up to 444% of maximum allowed at OEM	EES		X			X	X

21 CFR # / Name					Potential Hazards after Reprocessing * (see description of each category below)					
Listed FDA Pro Code	Device Type	510(k)	Findings / Observations	Report	Sterility	Energy	Biological	Environ-mental	Use	Functional
GEI	Electro. Shears	K925699	5 out of 5 devices tested exhibited debris on the patient-contact surfaces; two had blood and tissue on and under the clamp pad of the jaws	EES	X	X	X		X	X
GEI	Electro. Graspers	K910831	Failed the Dielectric Withstand Test, indicating a safety risk to the patient or the caregiver; original sheath removed and replaced	EES		X			X	X
878.4750 Implantable Staple										
GDW	Linear Cutter	K843034	Materials on several metal surfaces; instrument appears to have been fired, trigger handle was depressed, no cartridge in the instrument	McC	X	X	X	X	X	X
GDW	Linear Cutter	K843034	Mismatched parts; cracked and loose components	ADDM		X			X	X
GDW	Linear Cutter	K843034	Hole in inner and outer package	EES	X		X			
GDW	Linear Cutter	K843034	Hole in packaging	EES	X		X			
GDW	Linear Cutter	K843034	Autoclave sterilization caused device to be warped, partially melted and totally non-functional	EES					X	X
GDW	Linear Cutter	K843034	Corrosion on anvil; wear on the knife-edge; cracking and residues on patient-contact parts; tip of cartridge track broken off	EES		X	X		X	X
GDW	Linear Stapler	K890841	Mismatched parts; cracked and loose components	ADDM		X			X	X
GDW	Linear Stapler	K890841	Failed to fire all remaining staples	ADDM		X			X	X
GDW	Linear Stapler	K890841	Handle found in closed position; no cartridge	McC		X			X	X
878.4300 Implantable Clip										
FZP	Clip Applier	K820837	Only 13 clips - original device had 20	McC					X	X
FZP	Clip Applier	K820837	Inadequate clip count	ADDM					X	X

21 CFR # / Name					Potential Hazards after Reprocessing * (see description of each category below)					
Listed FDA Pro Code	Device Type	510(k)	Findings / Observations	Report	Sterility	Energy	Biological	Environ-mental	Use	Functional
878.4800 Manual Surgical Instrument for General Use										
MDM	Grasper	Exempt	Missing part	ADDM		X			X	X
MDM	Clamp	Exempt	Missing part and packaging label	ADDM		X			X	X
Boston Scientific										
Unknown	Biopsy forceps	Unknown	85% of product tested had obvious blemishes and/or defects	ADDM		X			X	X
Unknown	Biopsy forceps	Unknown	4 out of 5 tested not sterile	ADDM	X		X			
Unknown	Biopsy forceps	Unknown	17 out of 20 tested were not sterile	ADDM	X		X			
US Surgical Corp.										
Unknown	Skin Stapler	Unknown	Jammed after firing 10 of 25 remaining staples	ADDM		X			X	X
Unknown	Endo Retract	Unknown	1 out of 6 tested were not sterile	ADDM	X		X			
Unknown	Clip Applier	Unknown	Failure to fire all remaining clips	ADDM		X			X	X
Unknown	Stapler	Unknown	2 out of 6 tested were not sterile.	ADDM	X		X			
Unknown	Stapler	Unknown	Handle failed to return after firing	ADDM		X			X	X

Note: All devices listed are classified as "Critical Reprocessed Single Use Devices: reprocessed single-use device intended to contact normally sterile tissue or body spaces during use."

*** Identification of possible hazards**

Sterility **Hazards:**
Compromised sterility.

Energy **Hazards:**
Electricity, heat, mechanical force, ionizing radiation, non-ionizing radiation, electromagnetic fields, ***moving parts***, suspended masses, patient support device failure, pressure (vessel rupture), acoustic pressure, vibration and/or magnetic fields, e.g., MRI.

***Biological* Hazards:**
Bioburden, biocontamination, bioincompatibility, incorrect output (substance/energy), ***incorrect formulation*** (chemical composition), ***toxicity, (cross)-infection, pyrogenicity, inability to maintain hygienic safety, degradation.***

***Environmental* Hazards:**
Electromagnetic interference, inadequate supply of power or coolant, restriction of cooling, likelihood of operation outside prescribed environmental conditions, ***incompatibility with other devices***, accidental mechanical damage, ***contamination due to waste products / device disposal.***

Hazards related to the *use* of the device:
Inadequate labeling, inadequate operating instructions, inadequate specifications of accessories, inadequate specification of pre-use checks, over-complicated operating instructions, ***unavailable or separated operating instructions***, use by unskilled / untrained personnel, reasonably foreseeable misuse, insufficient warning of side effects, ***inadequate warning of hazards likely with reuse of single use devices***, incorrect measurement and other metrological aspects, incorrect diagnosis, erroneous data transfer, mispresentation of results, incompatibility with consumables / accessories / other devices.

Hazards arising from *functional* failure, maintenance, and aging:
Inadequacy of performance characteristics for intended use, ***lack of, or inadequate specification for maintenance***, including inadequate specification of post maintenance functional checks, inadequate maintenance, lack of adequate determination of end of device life, ***loss of mechanical integrity, inadequate packaging (contamination / deterioration of the device), improper reuse.***

** **Reports**

A report by McCrone Associates, Inc., Westmont, Illinois entitled "Microscopical Examination of Reprocessed Surgical Instruments" dated November 8, 2002. (listed as "McC" in the table)

An internal study by Ethicon Endo-Surgery, Inc. dated April 4, 2000 entitled "Evaluation of Reprocessed Single Patient Use (SPU) Devices." (consolidated with the October, 1999 study and listed as "EES" in the table)

An internal study by Ethicon Endo-Surgery, Inc. dated October, 1999 entitled "Evaluation of Reprocessed Single Patient Use (SPU) Devices." (consolidated with the April 4, 2000 study and listed as "EES" in the table)

Report by The Association of Disposable Device Manufacturers dated April 27, 1999 entitled "Evaluation of Safety and Performance of Reprocessed Single-Use Medical Devices, Experience of Three Medical Device Manufacturers: Ethicon Endo-Surgery, Inc., Boston Scientific Corporation, U. S. Surgical Corporation." (listed as ADDM in the table)

Conclusion

It is clear in these and other reports that reprocessing can compromise product and/or packaging integrity, putting subjects at increased risk. All of the reprocessed devices exhibited in the studies exhibited packaging and/or labeling deficiencies, with instructions for use, indications, precautions, warnings and contraindications missing. Damaged packaging was observed in which the contents of the package was potentially exposed to the environment over a third of the time. These defects compromise the sterile barrier and contradict the reprocessor's assurance of product sterility. Parts/components were missing in a great number of the devices. In one study, well over half the devices exhibited biological debris, sometimes identified as blood.

Reprocessing of Harmonic Scalpel blades, in particular, clearly compromised device integrity and subsequently the safety of the device and clearly put subjects at increased risk. In other electrosurgical devices tested, the reprocessor had tampered with the electrical insulating sheaths, clearly posing a risk to the patient or the caregiver.

Devices exempt from 510(k) filing as a newly manufactured device should require full validation testing and not be exempt from 510(k) filing if reprocessed because of increased risks once the device has been used.

Devices that deliver staples should not be exempt for the purposes of reuse but should be required to furnish validation data because of issues of cleaning and, therefore, sterilization, and because of the many instances of functional compromise upon reuse.

Based on these risks and the information derived from these studies, devices cited in the aforementioned table and mentioned in this Conclusion should be subject to full validation testing by the reprocessor and comprehensive validation data should be carefully evaluated by FDA as part of the 510(k) process before reprocessed devices are cleared for commercialization.

In closing, Ethicon Endo-Surgery, Inc. appreciates the opportunity to comment on the issue of the requirement for full validation testing for certain reprocessed single use devices.

Should you have any questions regarding these comments, please call me at 513-337-8205.

Respectfully submitted,

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Enclosures

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