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Food & Drug Administration
CDRH/OHIP/DSMICA (HFZ-220)
1350 Piccard Drive
Rockville, MD 20850-4307
Attn: Bill Sutton

Re: Docket No. 02N-0534

Dear Sir or Madam:

Boston Scientific Corporation (BSC) submits these comments in support of the listing of diagnostic electrophysiology catheters (EP catheters) and surgical radiofrequency (RF) ablation probes[1] as reprocessed, single-use devices for which validation data must be included in submissions made pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA) in accordance with Title III, Section 301(b)(1) of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

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The safety and effectiveness of reprocessed EP catheters and RF ablation probes cannot adequately be assured without including validation data in Section 510(k) premarket

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[1] For purposes of these comments, the generic term "EP catheters" is used to describe the medical devices regulated by FDA under product codes DRF ("electrode recording catheters") and MTD ("intra-cardiac mapping, high-density array catheters"). The term RF ablation probes is used to describe devices identified by FDA product code GEI (electrosurgical, cutting and coagulation devices and accessories). As the comments demonstrate, although the devices included in these product codes have different materials and design features and different functions and uses, they have important features in common that raise significant concerns regarding their safety and effectiveness on reuse.

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submissions. Validation data regarding cleaning, sterilization, and functional performance are necessary to establish the maximum number of times that these devices can be reprocessed and remain substantially equivalent to the single-use predicate device. Single-use, diagnostic EP catheters and RF ablation probes are designed only for first-use performance, not for amenability to cleaning and sterilization. These devices have delicate electrodes, sensors, wires, steering mechanisms and bonds that are vulnerable to breakage or cracking during repeated use and reprocessing. Moreover, EP catheters and RF probes are subject to repeated stress during initial use that may compromise the integrity and performance of the device on reprocessing and reuse. The diversity, complexity and continuing evolution of EP catheter and RF probe designs and materials require prior review of validation data for each type of these devices. Therefore, FDA should list diagnostic EP catheters and RF ablation probes as reprocessed, single-use devices for which validation data must be submitted pursuant to the premarket review provisions of Section 510(k) of the FFDCA.

I. FDA MUST IDENTIFY REPROCESSED, SINGLE-USE DEVICES FOR WHICH VALIDATION DATA ARE NECESSARY TO ENSURE THAT THE DEVICES ARE SUBSTANTIALLY EQUIVALENT TO THEIR PREDICATES AFTER REUSE

Pursuant to FDA regulations at 21 C.F.R. § 870.1220(b), electrode recording catheters and probes (including EP catheters) are classified as non-exempt Class II medical devices. Electrosurgical cutting and coagulation devices and probes (including RF ablation probes) are classified as non-exempt Class II devices pursuant to FDA regulations at 21 C.F.R. § 878.4400. These devices are not exempt from premarket review under section 510(k) of the FFDCA; however, FDA does not currently require the inclusion of validation data in submissions for reprocessing and reuse of single-use EP catheters and RF probes to demonstrate

the maximum number of times that these devices can be reprocessed and remain substantially equivalent to the single-use, predicate device.

Congress enacted Title III of MDUFMA in response to significant safety concerns regarding the reprocessing and reuse of devices that were approved by FDA for single-use only. Title III requires FDA to:

> [I]dentify [single-use devices for which reports are required under Section 510(k) that] must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data . . . regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.[2]

Under MDUFMA, FDA is required to "publish in the Federal Register list of the types [of devices] so identified . . . ."[3] Upon publication of the list, reports submitted pursuant to section 510(k) of the FFDCA must include validation data for the devices listed.[4] Such validation data are necessary to establish the maximum number of times that listed devices can be reprocessed and remain substantially equivalent to the single-use, predicate device.

II. SINGLE-USE DIAGNOSTIC EP CATHETERS ARE COMPLEX, CRITICAL DEVICES USED IN INVASIVE INTRA-CARDIAC PROCEDURES

Diagnostic EP catheters are used in invasive, intra-cardiac procedures to evaluate cardiac arrhythmias by assessing cardiac conduction and electrophysiology. These devices may remain in the heart for 2 to 4 hours or longer during a single procedure. Although various

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2 MDUFMA § 302(b)(1).

3 *Id.*

4 *Id.* Manufacturers and distributors of reprocessed single-use devices will have nine (9) months from the date on which a device is included on the list to submit to FDA validation data with respect to those devices for which a 510(k) report had previously been submitted. *Id.*

diagnostic EP catheters have different structural configurations, are composed of different materials and may be utilized for different purposes, they nonetheless have a number of common structural features that raise similar concerns with respect to their safety upon repeated reuse.

A. General Design Features and Use Patterns of EP Catheters

EP catheters are typically 100 to 125 cm in length, have as many as 64 electrodes, and include numerous sensors, electrical wires, and others delicate components. Steerable EP catheters also include a complex, bi-directional steering mechanism; fixed curve catheters have curve profiles that are precisely configured and optimized for targeted sites within the heart. Additionally, many catheters are composed of dissimilar materials that are bonded with adhesive or heat. EP catheters also may include design features resulting in areas that are difficult to access, such as acute angles, crevices, joints, coils, reinforcing meshes, rough, porous or occluded surfaces, and long, narrow lumens. Finally, the catheters may be composed of materials, such as nitinol or polyurethane, that may undergo compositional changes during reprocessing.

B. Specific Design Features and Use Patterns of EP Catheters

EP catheters have a wide variety of configurations and uses. As a result, particular types of EP catheters may have structural and design features that give rise to particular device integrity or disinfection concerns on reprocessing. The functions and attributes of particular types of EP catheters are described below. [5]

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[5] Diagrams of a typical fixed curve, steerable, and advanced mapping catheters are included in Attachment 1.

1. Fixed Curve and Steerable Diagnostic EP Catheters

Fixed-curve and steerable diagnostic EP catheters are used to diagnose potential cardiac arrhythmias, including both bradyarrhythmias and tachyarrhythmias. A complete step-by-step procedure is conducted to assess the components of the cardiac conduction system and to define cardiac electrophysiology. A baseline electrophysiology study is an invasive, sterile procedure that may last for 2 to 4 hours or longer. Two to five or more catheters are placed into the right side of the heart, typically through the femoral vein, although other access sites – such as the subclavian vein, internal jugular vein or femoral artery – may also be used. Electrodes typically are placed in the high right atrium, near the sinus node, the area of the His bundle, the coronary sinus that lies in the posterior atrioventricular groove and near the left atrium and ventricle, and in the right ventricle. The electrodes at the flexible, distal end of the catheter pace the heart and detect intracardiac electrical impulses that are relayed to a central console through electrical wires.

Because diagnostic electrophysiology studies involve catheter placement in multiple areas within the heart, catheter design is critical to site access. Due to varying anatomical conditions, particular catheters are designed and configured for specific cardiac locations. Some catheters have fixed curves that are precisely optimized to reach targeted sites within the heart. Steerable catheters have a control mechanism in the device handle that is designed to maneuver and position the catheter tip to reach a variety of anatomical locations within the heart. During a single two hour procedure, a steerable catheter may be moved to as many as 200 locations.

2. Advanced Mapping EP Catheters

Advanced mapping EP catheters are designed for mapping the heart chambers to diagnose complex, intermittent or unstable arrhythmias. These conditions may be difficult to identify using traditional point-by-point techniques in which a diagnostic EP catheter is moved to multiple sites to obtain mapping information. Advanced mapping catheters are typically deployed into the heart chamber and remain in contact with the desired location throughout the 2 to 4 hour procedure. Advanced mapping catheters can be fixed or steerable and typically have between 10 and 64 electrodes. Examples include 10 to 24 electrode fixed and steerable atrial mapping catheters, a "basket" configuration composed of 64 electrodes on eight splines, and reference catheters that combine basic EP diagnostic functions with advanced mapping and navigation techniques.

III. REPROCESSING SINGLE-USE EP CATHETERS PRESENTS A HIGH RISK TO PATIENT SAFETY AND DEVICE EFFECTIVENESS

Single-use EP catheters are designed for optimal performance on first-use, rather than to withstand repeated use or for ease of cleaning and sterilization. There are three principal concerns associated with the repeated reuse and reprocessing of single-use EP catheters. First, due to the design features of particular EP catheters, their structural integrity may be compromised by reprocessing and reuse. Second, existing sterilization methods may not adequately disinfect reprocessed, single-use EP catheters. Finally, sterilization processes may change material composition and result in residues that may compromise device effectiveness and present a risk to patient safety.

A. Due to Their Design and Use Patterns, The Structural Integrity of Single-Use EP Catheters May Be Compromised by Reprocessing and Reuse

1. Catheter Design Features

EP catheters are designed to be very small, very long, and very flexible and maneuverable. They include complex assemblies of precision components, electrodes, wires, sensors, and steering mechanisms. As a result, the structural integrity of all types of single-use EP catheters may be seriously compromised or destroyed by cleaning, sterilization and repeated use. Indeed, the primary concern with respect to reuse of EP catheters is the "mechanical and physical change experienced by catheter material after it has been used in the human body."[6]

Some EP catheters are comprised of two different materials – a firm proximal shaft and a softer, more flexible distal segment – bonded together with adhesive or heat. This bond represents a weak point in the device's construction and repeated bending and stress during use may cause cracks or breaks in the bond. Reprocessing may further stress and weaken the bonds between catheter components. Blood, bacteria, viruses and other organic matter may collect and accumulate in cracks or crevices in the bond or other imperfections in the device caused by stress and/or reprocessing. In addition to presenting a risk of infection or other adverse health effects to patients, the presence of foreign matter may interfere with the effective operation of the device, causing it to break or malfunction.

Steerable catheters may be particularly prone to structural breakdown on reuse and reprocessing, due to the complexity of the steering mechanism and the inherent need for flexibility in their design. Steerable catheters undergo numerous steering cycles as they move to

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[6] Beck, A. *Potential Reuse? A Study of the Reuse of Catheters, Guidewires and Angioscopes*, 12 (1993).

different parts of the heart in a single procedure. Repeated flexing of the steerable catheter shaft may cause cracks in the bond. It may also break or damage the internal wires of the shaft and the steering mechanism and its attached electrical wires, causing a risk of patient injury.

Advanced mapping and reference catheters are the most technically complex EP catheters. This technical complexity – some catheters of this type include up to 64 separate electrodes – makes them especially vulnerable to malfunction after reprocessing. EP catheters having more than ten electrodes are particularly vulnerable to equipment malfunction during reprocessing and reuse. For example, the BSC Constellation mapping catheter has 64 electrodes and an equal number of separate, very fine wires that must maintain functional integrity in order to operate. The catheter electrodes are incorporated into eight splines constructed from the shape-memory alloy, nitinol. The ribbons are sheathed in ultra-thin electrical insulating sheath and encased within a polymer tube jacket on which the electrodes are mounted and arranged in a basket configuration through a central lumen at the catheter tip. The electrode wires are routed through the tiny space between the insulating sheath and the polymer jacket.

These assemblies are designed to maintain continuous, intimate contact with the endocardial tissue within the interior of the heart. The assembly flexes and relaxes with the powerful contractions of the cardiac muscle over thousands of heartbeats, causing repeated stress and assembly fatigue. In a single two-hour procedure (assuming a heart rate of 90 beats per minute), the device will undergo 10,800 flex cycles, which can stress and fatigue bonds and delicate metal components. Newly manufactured, single-use advanced diagnostic mapping catheters are validated in flexural testing to a four-fold safety factor (40,000 flex cycles at 30 percent extension). The cumulative effect of prior clinical use, various patient anatomies and

procedures, rehandling, resterilization and reuse increases the likelihood that the catheters may break, increasing patient risk. It is therefore essential that these cumulative effects be evaluated in validation studies to establish safety limits for the maximum number of times the device may be safely reprocessed and reused.[7]

2. Data

The available data demonstrate the deleterious impact of reprocessing and reuse on the structural assembly of EP catheters. For instance, a 1993 study of deflectable ablation catheters – which are closely related to EP catheters in structure and design – indicated a high rate of failure after reprocessing.[8] This study evaluated 69 deflectable ablation catheters used in 336 procedures over a one-year period. Each device was inspected between uses, and 59% were eventually rejected. The authors noted various failure modes, including tip electrode glue separation, loss of deflection, and electrical discontinuity after multiple reprocessing. The authors also noted deep pitting of the catheter tip electrode and small fractions of missing polyurethane glue, which may have been released into patients' bloodstreams. Further, blood that had collected in spaces where glue was missing could not be removed using normal sterilization and cleaning techniques.[9]

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7 Original manufacturers of single-use EP catheters also conduct extensive functionality testing at a sequence of predetermined shelf-life time periods. These data are used to establish the shelf-life time period and expiration date for the product. Reprocessors should similarly validate device-integrity over the shelf-life of the reprocessed device to support any change to the original expiration date.

8 Avitall, B.; Khan, M.; Krum, D.; Jazayeri, M.; Hare, J. Repeated Use of Ablation Catheters: A Prospective Study. *J. American College Cardiology* 22:1367-1372 (1993).

9 *Id.*

A report by Blomstrom-Lundqvist of the results of reprocessing at one hospital demonstrated similar results.[10] Of the 74 reprocessed EP ablation catheters included in the study, 41 (55%) were rejected due to breakage or defects in internal pulling wires, problems with electrogram readings, insufficient deflection capability and inaccurate temperature readings. All but the latter would similarly apply to EP diagnostic catheters. Of particular note, the hospital discarded one catheter because it had been used on a patient known to have hepatitis, calling into question the hospital's confidence in its own cleaning and sterilization program. The author concluded that "multiple uses and reprocessing may have adverse effects on the characteristics or quality of the catheter leading to unsafe and ineffective patient treatment."[11]

B. Reprocessing Methods Must Be Validated to Assure the Cleanliness, Sterility and Compositional Integrity of Reprocessed, Single-Use EP Catheters

As discussed above, the design, structural features and composition of single-use EP catheters may contain areas that are difficult to access, including acute angles, crevices, joints, coils, electrodes, reinforcing meshes, and, in some cases, open lumens or complex steering mechanisms. These areas create barriers to cleaning and sterilization and may allow for the collection of bacteria, viruses, blood and other organic matter. Therefore, reprocessing and reuse of single-use EP catheters may create a risk of contamination of the device and cause patient infection or other adverse affects as the result of the transmission of infectious or pyrogenic materials from one patient to another. Moreover, the introduction of foreign organic or inorganic matter into the heart or blood stream on subsequent use may also lead to embolus formation, which can cause a serious or fatal stroke.

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10 Blomstrom-Lundqvist, C. Reuse of Catheters for Invasive Electrophysiological Procedures. *Eur. Heart J. Suppl.* 1:G15-G19 (1999).

11 *Id.*

Sterilization methods must therefore be validated to ensure the consistent sterility of reprocessed, single-use devices. Most reprocessors use ethylene oxide gas to sterilize single-use EP catheters. Ethylene oxide sterilization is a bioburden-based method and its effectiveness is limited by the inability of ethylene oxide gas to penetrate tissue. To ensure effective ethylene oxide sterilization, it is essential to ensure that the bioburden is consistently below that needed to achieve the sterility assurance level (SAL) of 10^{-6}.[12] The bioburden on used EP catheters may vary significantly, depending on such factors as the device configuration, length and nature of the procedure, and the presence of infection. Validation of sterilization processes for each type of device is therefore essential to ensure that reprocessed catheters do not exceed the SAL.

While ethylene oxide sterilization may be effective in sterilizing some types of EP catheters, it may leave toxic ethylene oxide residues or cause compositional changes in the catheters' assemblies. A study of 12 ethylene oxide-sterilized, reprocessed EP catheters assessed (among other things) microbiological contamination and the prevalence of carcinogenic ethylene oxide residue after sterilization.[13] While the three catheters tested for microbiological contamination were deemed sterile, problems with particulate and chemical residues were noted. Moreover, all six catheters tested for residues contained levels of residual ethylene oxide that exceeded federal standards following ethylene oxide sterilization for two hours and aeration for as long as 14 days. Moreover, the authors cautioned that "fluid entrainment around the distal

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12 The SAL is the level at which there is a one in a million chance that a device is non-sterile. *See, e.g.,* BSEN Standard No. 556, "Sterilization of Medical Devices: Requirements for Medical Devices to be considered Sterile," Section 4.1.

13 Aton, E.A.; Murray, P.; Fraser, V.; Conaway, L.; Cain, M.E. Safety of Reusing Cardiac Electrophysiology Catheters. *Am. J. Cardiol.* 74:1173-1175 (1994).

pole may occur in catheters with tip electrodes."[14] Other effects of ethylene oxide sterilization may include corrosion, loss of sharpness, oxidation, alkylation, and absorption of toxic ethylene oxide residues.[15] Therefore, while ethylene oxide sterilization may successfully sterilize some EP catheters, it cannot consistently and adequately assure the integrity, effectiveness and safety of reprocessed, single-use EP catheters.

Other commonly-used sterilization methods are unlikely to be effective in sterilizing used EP catheters. Steam sterilization is unlikely to be effective because the electronic and composite material components of EP catheters malfunction or melt if subjected to the extremely high temperatures of this technique. Similarly, the use of radiation treatment to sterilize EP catheters likely would destroy the physical integrity of the devices.

Hydrogen peroxide gas plasma sterilization has been proposed as a promising alternative to ethylene oxide sterilization for reprocessing used EP catheters.[16] This method has not, however, been demonstrated to reproducibly achieve a 10^{-6} SAL for EP catheters. Nor has it been shown to be effective against virus infections such as HIV and hepatitis.[17] Finally, this method has not been shown to maintain the integrity of the device. Indeed, one study of

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14 *Id.*

15 *See* Lerouge, S.; Guignot, C.; Tabrizian, M.; Ferrier, D.; Yahia, L.H. Plasma-based Sterilization: Effect on Surface and Bulk Properties and Hydrolytic Stability of Reprocessed Polyurethane Electrophysiology Catheters. *J. of Biomed. Materials Research* 52:774-782 (2000).

16 *Id. See also* Blomstrom-Lundqvist *et al.* (1999).

17 Blomstrom-Lundqvist *et al.* (1999). Moreover, it should be noted that prions, which may infect the central nervous system and cause spongiform encephalopathies such as Creutzfeld-Jakob disease, do not appear to be destroyed by traditional sterilization methods used to destroy bacterial and viral pathogens. As FDA has stated, "routine materials and processes that destroy traditional human and animal pathogens do not appear to destroy prions. Presently, no established methods can reliably decontaminate or sterilize articles contaminated with prions." FDA Action Plan: Transmissible Spongiform Encephalopathies including Bovine Spongiform Encephalopathy and Chronic Wasting Disease (April 24, 2001).

polyurethane EP catheters reported oxidation of the near-surface layer and alteration of the oligomer profile following plasma sterilization.[18]

Reprocessing may result in compositional changes in materials such as nitinol and polyurethane commonly used to produce EP catheters. A number of commercially-available, high-performance, single-use diagnostic EP catheters owe much of their high performance to the use of a superelastic nitinol (nickel-titanium) alloy in their construction. This group of catheters includes Boston Scientific's "Constellation™", Irvine Biomedical's "AFocus™", and Biosense-Webster's "Lasso™", among others. The mechanical structure and integrity of the distal portion of these catheter is determined largely by the structure and integrity of the nitinol member used in that section.[19]

The cleaning, reprocessing, and reuse of nitinol-based catheters raises several concerns. First, the metalurgical structure of nitinol is permanently altered when it is flexed repeatedly during use as is the case with the catheters listed above. When subjected to repeated flexing, the nitinol in these catheters becomes brittle and will eventually fracture. The inevitable structural alteration of nitinol due to flexing is commonly referred to as "flex fatigue" or "work hardening". When fracture occurs, the mechanical structure of the catheter may be lost, sharp broken edges or points may result, and the catheter may become difficult or impossible to remove via its entrance route, leading to loss of efficacy and potentially serious patient injury. These catheters are designed and extensively tested to minimize the potential for fracture during the catheter's intended use during a single electrophysiology procedure. The potential for

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[18] Lerouge *et al.* (2000).

[19] *See generally* Vezeau, P.; Koorbusch, G.; Draughn, R.; Keller, J. "Effects of Multiple Sterilization on Surface Characteristics and In Vitro Biologic Responses to Titanium." *J. Oral Maxillofac. Surg.* 54:738-746 (1996).

fatigue and fracture is substantially increased if catheters containing nitinol are reprocessed. Validation should be required to demonstrate that any catheter containing nitinol can be reprocessed safely without loss of mechanical integrity.

Nitinol also reacts strongly with solutions containing any form of acidic halide such as chloride, bromide or iodide. When the metal comes into contact with acid halide solutions, it corrodes rapidly and becomes brittle. This greatly accelerates the process described above and, in severe cases, makes fracture during the next use virtually inevitable. Acidic halides are common components of hospital and laboratory cleaning and disinfecting solutions. It is therefore important that reprocessors conduct validation studies to demonstrate the continued structural integrity of nitinol-containing catheters exposed to these materials during reprocessing to demonstrate their continued safety and effectiveness on reuse.

Polyurethanes, which also are commonly used in the construction of EP catheters, may also degrade when subject to irradiation or steam sterilization and may undergo oligomer modification following plasma-based sterilization.[20] FDA studied used angioplasty and EP catheters that were collected from Walter Reed Army Medical Center, cleaned and resterilized with ethylene oxide.[21] This study demonstrated that subtle changes in product composition affected the ability to clean the devices. Reprocessing had different effects on different polyurethanes used in different catheter models. One polyurethane became more brittle in bleach, while the other became more flexible. The author noted that these studies highlight the complexity of conducting the validation studies needed to reuse single-use devices and

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20 *See* Lerouge *et al.* (2000).

21 OR Manager 15:9 (July 1999).

concluded that "validation studies must be done, not only for each and every device, but for each model as well."[22]

IV. FDA HAS RECOGNIZED THAT REPROCESSED EP RECORDING CATHETERS POSE A HIGH DEGREE OF RISK TO PATIENTS

In February 2000, FDA published a draft guidance document setting forth its enforcement strategy for reprocessing and reusing single-use devices.[23] The draft Review Prioritization Scheme (RPS) set forth a flow chart and questionnaire by which reviewers could determine the risk category of reprocessed single-use devices. FDA developed the risk categories to evaluate the "risk of disease transmission during reuse of a reprocessed [single-use device]."[24] The RPS evaluated the two types of risks that may arise as a result of the reprocessing and reuse of a single-use device: (1) the risk of infection; and (2) the risk of inadequate or unacceptable device performance. Based on these criteria, the RPS placed reprocessed single-use devices into low, moderate, or high overall risk categories. Those devices that posed the greatest risk of infection and that were most likely to malfunction after reprocessing were classified as "high risk." Using the RPS, FDA identified reprocessed, single-use EP recording catheters as high risk devices.[25]

FDA subsequently decided to use established regulatory classifications for medical devices (Class I, II, or III) rather than the RPS risk categories as the basis for its

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22 *Id.*

23 *See* FDA, "Draft Guidance for Industry and FDA Reviewers: Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" (February 8, 2000).

24 *Id.*

25 *Id.*

enforcement strategy.[26] Nonetheless, FDA's risk categories remain a useful tool for identifying high risk devices. As FDA's own risk analysis demonstrates and these comments confirm, the continued safety and effectiveness of reprocessed, single-use EP catheters cannot reasonably be assured without the requirement that validation data be included in submissions made pursuant to Section 510(k).

V. VALIDATION DATA ARE REQUIRED TO ENSURE THE CLEANLINESS, STERILITY AND INTEGRITY OF REPROCESSED, SINGLE-USE RF ABLATION PROBES

RF ablation probes are single-use devices designed for use during open, general surgical procedures to coagulate soft tissue by the use of heat. Surgical probes may also be used to coagulate blood and soft tissue to produce hemostasis. A typical RF probe has approximately 7 electrodes, with a distal tip electrode length of 8 mm. The distance between electrodes is approximately 2 mm. The shaft length of such a device is usually 21 cm, and the effective ablation length varies from 10 mm to 95 mm. The coil electrode length of surgical probe catheters is approximately 12.5 mm.[27]

A study conducted for BSC evaluated 29 used and reprocessed ablation probes using microbiological methods, the radioneucleotide method and microstructural analyses to characterize cleaning conditions and materials changes.[28] The study reported that two of the ten (20 percent) devices tested following disinfection and one of six (16.7 percent) devices tested following sterilization showed the presence of microorganisms. After reprocessing, nine of nine

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26 *See* FDA, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (August 14, 2000).

27 A diagram of a typical RF ablation probe is included in Attachment 2.

28 PMP, "Report of Tests on Thermaline™ Surgical Probe after Simulated Use and Reprocessing" (12 May 1999). A copy of the study report is included in Attachment 3.

(100 percent) devices tested with the radionuclide method showed contamination. Microstructural analyses demonstrated massive contamination, especially in the space between the metallic coils of the devices, and some structural changes were noted in the used devices. Finally, the authors reported delaminations of adhesive and gaps at the bonding locations.[29] These data demonstrate the difficulty of adequately cleaning and sterilizing used RF ablation probes. The study also demonstrates the potential for damage to the structural integrity of the devices due to use and reprocessing. As a result, validation data are necessary in 510(k) submissions for reprocessed RF ablation probes to demonstrate their continued safety and effectiveness up to a maximum number of uses.

VI. CONCLUSION

MDUFMA requires FDA to evaluate reprocessed, single-use devices subject to the premarket notification requirements of Section 510(k) of the FFDCA and identify those for which validation data regarding cleaning, sterilization, and functional performance should be submitted to demonstrate the maximum number of times these devices can be reprocessed and remain substantially equivalent to the single-use predicate device. Reprocessed, single-use EP catheters and RF ablation probes are reprocessed, single-use devices that present a high degree of risk to patients. The complex assemblies and highly technical components of these devices are not designed to withstand reprocessing; and sterilization and/or cleaning procedures may destroy their structural integrity. Further, the design and structural features of EP catheters and RP probes may prevent adequate cleaning and removal of residual biological material from these devices, creating the risk of device malfunction or cross-contamination of patients. Reprocessing

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29 *Id.*

methods are generally not adequate to ensure the sterility of EP catheters or RF probes without damaging their effectiveness.

Validation data are therefore essential for reprocessed, single-use EP catheters and RF ablation probes to provide reasonable assurances of these devices' continued safety and effectiveness to a maximum number of reuses. Thus, MDUFMA requires that EP catheters falling within product codes DRF and MTD and RF ablation probes in product code GEI be included on the list of devices for which such validation data must be submitted. As a result, BSC urges FDA to list reprocessed single-use EP catheters and RF probes pursuant to Section 301(b)(1) of MDUFMA.