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Citizen Petition

Hyman, Phelps & McNamara, P.C. ("HP&M") submits this petition pursuant to section 510(o) of the Federal Food, Drug, and Cosmetic Act ("FDC Act")¹ and 21 C.F.R. § 10.30. HP&M requests that the Commissioner of Food and Drugs take action to require manufacturers of reprocessed single-use electrosurgical cutting and coagulation devices and accessories² to submit validation data, including cleaning, sterilization, and functional performance data, demonstrating that each device will remain substantially equivalent to its predicate device after the maximum number of times the device is intended to be reprocessed.

¹ 21 U.S.C. § 360(o)

² These devices, which are classified in 21 C.F.R. § 878.4400, are described in more detail in Section B.2.a. below.

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A. Action Requested

HP&M requests that the Commissioner of Food and Drugs take the following action:

(1) publish a notice in the Federal Register adding electrosurgical cutting and coagulation devices and accessories to “List II – Reprocessed Single-Use Devices Subject to Premarket Notification Requirements That Will Now Require The Submission of Validation Data;”

(2) require manufacturers of reprocessed single-use electrosurgical cutting and coagulation devices and accessories with cleared or pending premarket notifications (also referred to as “510(k)s”) to submit validation data regarding cleaning, sterilization, and functional performance for these devices within nine months of the publication of the Federal Register notice in (1); and

(3) require manufacturers of reprocessed single-use electrosurgical cutting and coagulation devices and accessories who submit 510(k)s after the publication of the Federal Register notice in (1) to include validation data regarding cleaning, sterilization, and functional performance as part of their 510(k) submissions for these devices.

B. Statement Of Grounds

1. Legal Framework

The Medical Device User Fee and Modernization Act of 2002 (“MDUFMA”)³ amends section 510 of the FDC Act to require the submission of validation data for certain categories of reprocessed single-use devices.⁴ Section 510(o)(1) of the FDC Act, which was added by MDUFMA, requires the Food and Drug Administration (“FDA”) to identify reprocessed single-use devices or types of devices for which premarket notifications are currently required and for which validation data regarding cleaning, sterilization, and

³ Pub. L. 107-250.

⁴ MDUFMA contains distinct requirements for reprocessing single-use devices that are subject to the 510(k) requirement and those that are exempt from the 510(k) requirement. Because the devices that are the subject of this petition require 510(k)s when new or reprocessed, this petition will not address the requirements for exempt devices.

functional performance must be included as part of the premarket notification submission in order to demonstrate 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.”⁵ The statute required FDA to publish a list of the types of devices that it identifies as requiring validation data within six months after enactment.⁶ The statute further directs FDA to “revise the list as appropriate.”⁷ Upon publication or revision of the list, premarket notifications submitted for newly-listed reprocessed single-use devices are required to include validation data.⁸ For premarket notifications that were submitted prior to inclusion of the device on the list, manufacturers are required to supplement the pending or cleared 510(k) with validation data no later than nine months after publication of the list.⁹

In April 2003, FDA published the required list identifying types of reprocessed single-use devices already subject to premarket notification requirements that would now require validation data for a determination of substantial equivalence (“List II”).¹⁰ List II does not currently include electrosurgical cutting and coagulation devices.

In deciding which devices to include on List II, FDA assigns a risk level based on its analysis of the reprocessed device through the Review Prioritization Scheme (“RPS”) it described in a February 2000 draft guidance document titled “Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme” (“RPS Guidance”). The RPS Guidance assigns an overall risk to reprocessed single-use devices based on the risk of

⁵ 21 U.S.C. § 360(o)(1)(A).

⁶ Id.

⁷ Id.

⁸ Id.

⁹ Id. § 360(o)(1)(B).

¹⁰ “Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data,” Notice, 68 Fed. Reg. 23,139 (April 30, 2003) (“Initial List Publication Notice”). At the same time, FDA published a related list for previously exempt reprocessed devices (“List I”). Id.

infection and the risk of inadequate performance following reprocessing. The risk categories are high, moderate, and low. FDA also determined that single-use devices intended to come in contact with tissue at high risk of being infected with the causative agents of Creutzfeldt-Jakob Disease (“CJD”) would be subject to the MDUFMA validation data requirements.¹¹ Reprocessed single-use devices that are either high risk under the RPS or intended to come in contact with causative agents of CJD are placed on List II and require validation data to be submitted.¹² Devices that are considered moderate or low risk are not placed on List II.

The statute provided, and FDA recognized, that the lists may need to be reevaluated and updated over time.¹³ In June 2003, FDA did just that when it revised List I, the related list for previously exempt reprocessed devices, to add nonelectric gastroenterology-urology biopsy forceps.¹⁴ List II has not been updated.

¹¹ Id.

¹² Id. at 23141. MDUFMA and FDA make distinctions among critical, semi-critical, and non-critical devices. 21 U.S.C. § 321(mm)(1), (2); Initial List Publication Notice, 68 Fed. Reg. at 23140. These distinctions are taken into account in the RPS for the creation of List II. Note, however, that the devices in List II may be critical, semicritical, or noncritical.

¹³ 21 U.S.C. § 360(o)(1)(A); Initial List Publication Notice, 68 Fed. Reg. at 23141.

¹⁴ List I contains reprocessed single-use devices previously exempt from premarket notification requirements that, pursuant to FDA’s determination under MDUFMA, require 510(k)s with validation data. FDA published the list for critical devices on April 30, 2003, Initial List Publication Notice, List I, 68 Fed. Reg. at 23,141. In June 2003, FDA recategorized nine device types from semi-critical to critical. Because one of the nine device types – nonelectric gastroenterology-urology biopsy forceps – was considered high risk under the RPS, it was added to List I. “Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data,” Notice, 68 Fed. Reg. 38,071 (June 26, 2003).

2. Application of Legal Framework to Electrosurgical Cutting and Coagulation Devices
 - a. Electrosurgical Cutting and Coagulation Devices

Electrosurgical cutting and coagulation devices and accessories are Class II medical devices “intended to remove tissue and control bleeding by use of high-frequency electrical current.” 21 C.F.R. § 878.4400. This broad description includes six product codes (HAM, GEI, JOS, JOT, DWG, and BWA) with such specific devices as

- bipolar forceps, which permit diagnostic sampling and coagulation of tissue in minimally invasive procedures;
- electrosurgery probes, which facilitate tissue dissection, coagulation, irrigation, and fluid evacuation;
- endoscopic instruments, which facilitate grasping, mobilization, dissection, and transaction of tissue;
- microdissection needles used for soft tissue dissection in tonsillectomy and blepharoplasty; and
- electrothermal generators used to create lesions in nerve tissue and to coagulate and decompress disc material.

These devices are complex both in functionality and design, are made from many components and materials, and have difficult to reach areas such as lumens.

- b. Study Results Indicate that Reprocessed Electrosurgical Cutting and Coagulation Devices Present a High Risk to Patients

Numerous studies have been conducted that assess the cleanliness and integrity of reprocessed single-use devices, including electrosurgical cutting and coagulation devices. While these studies do not lend themselves to statistical tabulation of results for the subset of electrosurgical cutting and coagulation devices, the qualitative results do confirm the high risk nature of these products and the need for validation data to assure that the devices are substantially equivalent to the predicate device. Four studies, which specifically include reprocessed electrosurgical cutting and coagulation devices, are especially

relevant.¹⁵ In each study, reprocessed single-use devices were obtained in the unopened reprocessor packaging from hospitals where they were intended to be used in patient procedures. Packaging defects, residual debris, and performance failures were reported among the problems for the electrosurgical cutting and coagulation devices.

Packaging. Unlike the validated packaging used by Original Equipment Manufacturers (“OEMs”) to immobilize and cushion most electrosurgical cutting and coagulation devices, reprocessor packaging permitted device migration and failed to adequately protect packaging from sharp device edges. Electrosurgical devices with pointed distal ends were shipped without protective tips. As a result, reprocessed devices exhibited package quality failures including punctures, seal damage, and tears. These defects were sufficient to expose the device to the environment outside the packaging, thereby compromising sterility. In addition to these severe packaging failures, some packages exhibited “tenting” or physical strain at the point of contact with some angular and prominent device features such as end-effectors (e.g., blades, scissors, graspers). Tenting indicates a weak point in the package that is more susceptible to tearing upon subsequent contact.

Residual Debris. Many electrosurgical cutting and coagulation devices also exhibited debris, including residual blood and tissue, on patient contact surfaces. Analysis of the debris amongst all devices also revealed the presence of acrylic resin, cellulose, red cotton fiber, alkyl enamel, polystyrene acrylate, protein, chlorine, and iron oxide. This debris is indicative of poor cleaning, contamination with other devices, failure to remove residual cleaning fluid, and metal corrosion. Some devices were not sterile. This may have been due to debris lodged in difficult to reach areas that could prevent penetration of sterilization gases.

Performance. Of the devices tested for product condition, many were physically damaged or missing components. Product integrity analyses uncovered bent shafts in

¹⁵ Evaluation of Reprocessed Ethicon Endosurgery, Inc. Single-Use Medical Devices (January 1999); Evaluation of Safety and Performance of Reprocessed Single-Use Medical Devices: Experience of Three Medical Device Manufacturers (April 1999); Field Quality Engineering Report: Evaluation of Reprocessed Ethicon Endosurgery Single Patient Use Devices (October 1999 and April 2000); Microscopical Examination of Reprocessed Surgical Instruments (November 2002). See Attachments A-D.

electrosurgical cutting and coagulating devices, including one curved scissors with unipolar cautery that was bent to approximately 35° off the axis. In addition to bowed shafts, electrosurgical scissors evidenced dull and bent scissors, which failed to cut test material.

Testing of the reprocessed electrosurgical cutting and coagulation devices revealed excessive force necessary to actuate the devices. Many reprocessed scissors and shears were difficult to open and close, requiring up to 444% of the OEM's permitted actuation forces, likely due to lack of lubricant. Additional defects included blemished and improperly sharpened blades, damaged tooth profiles, torn clamp pads, and rough alignment pins.

Numerous electrosurgical devices showed evidence of damaged or altered electrical insulating sheaths. In some instances, the original sheaths had been completely replaced with a polymer whose dielectric constant is significantly lower than that of the original sheath material. On one electrosurgical curved scissor, the protective sheath had receded, exposing an enlarged area of potential patient contact with the electrical current.

c. **Electrosurgical Cutting and Coagulation Devices Are High Risk Under the Review Prioritization Scheme**

The RPS Guidance sets forth a series of questions and flowcharts to be used in determining whether a reprocessed single-use device presents a low, moderate, or high risk of infection or inadequate performance. In its April 30, 2003 Federal Register notice, FDA indicated that reprocessed electrosurgical cutting and coagulation devices are moderate risk devices under the RPS. However, when evaluated under the RPS, these devices must be categorized as presenting a high risk of both infection and inadequate performance. Because the Federal Register notice does not provide a discussion of FDA's evaluation of reprocessed electrosurgical cutting and coagulation devices, we are not able to determine what data FDA used categorizing the products and whether or in which way our analysis differs from FDA's analysis. As such, we set forth our analysis here.

(1) Evaluation of Risk of Infection

Flowchart #1 in the RPS Guidance includes six questions designed to assess the risk of infection presented by a particular reprocessed single-use device.

Question 1. Are electro-surgical cutting and coagulation devices non-critical devices?

No. As recognized by FDA in the April 30, 2003 Federal Register Notice, electro-surgical cutting and coagulation devices are critical devices as defined by the Spaulding criteria because they are intended to contact normally sterile tissue or body spaces during use and therefore present the greatest risk of disease transmission.

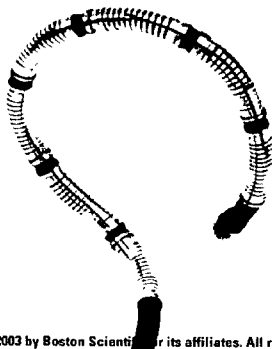
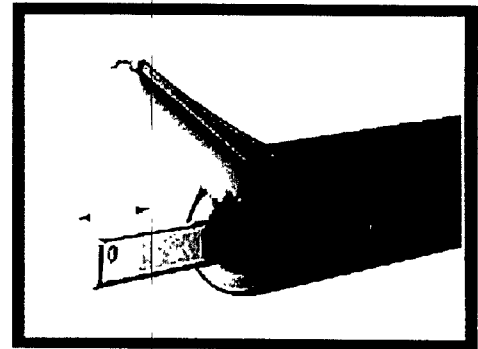
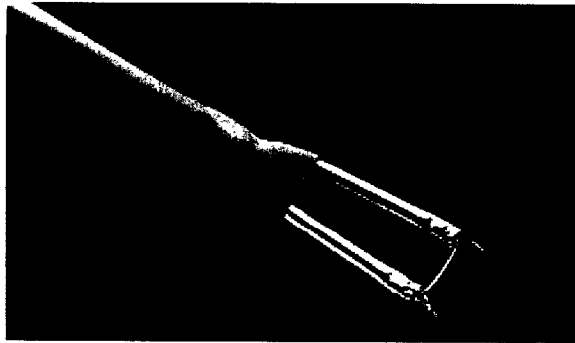
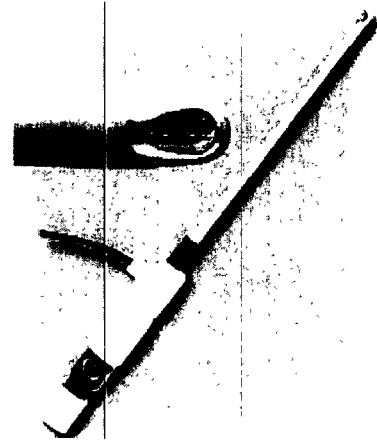
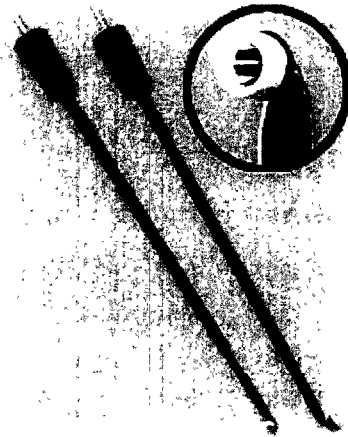
Question 2. Does postmarket information suggest that using reprocessed electro-surgical cutting and coagulation devices may present an increased risk of infection when compared to electro-surgical cutting and coagulation devices that have not been reprocessed?

Yes. As noted in Section B.2.b, several studies of reprocessed single-use electro-surgical cutting and coagulation devices have identified dried blood, body fluids, and other tissue, likely from the previous patient, on these devices. Moreover, on some devices, this tissue was lodged in areas that could prevent penetration of sterilization gases. The contaminants present a risk of infection and disease transmission during reuse that is not associated with a device that has never been used and reprocessed. In addition, these studies identified packaging defects including tears, punctures, and compromised seals, all of which result in failure of the sterile barrier and increased risk of patient infection.

Having determined that the response to Question 2 is “yes,” Flowchart #1 directs a conclusion that reprocessed electro-surgical cutting and coagulation devices present a high risk of infection. Even without these postmarket data, however, the devices are properly categorized as high risk. To demonstrate this point, we will continue our analysis of these devices under Flowchart #1.

Question 3. Do electro-surgical cutting and coagulation devices include features that could impede thorough cleaning and adequate sterilization/disinfection?

Yes. Electro-surgical cutting and coagulation devices are multifunctional instruments which offer a choice of modes for clamping, coagulating, dissecting, and cutting tissue, vessels, and vascular structures. As can be seen in the pictures below, electro-surgical cutting and coagulation devices, including coagulating shears, linear cutters, and curved scissors, contain inaccessible interlocking parts that cannot be disassembled, unremovable protective sheathing, temperature sensors, lumens, and narrow, creviced spaces.



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As noted by the RPS Guidance, these spaces can harbor debris that cannot be readily accessed and removed because not all device surfaces can be exposed for manual cleaning. This residual debris can then render sterilization steps unsuccessful and lead to a higher potential for disease transmission.

Question 4. Does a reusable device exist that has an equivalent design and the same intended use as single-use electrosurgical cutting and coagulation devices?

No. While reusable electrosurgical cutting and coagulation devices do exist, those devices do not have a design equivalent to single-use electrosurgical cutting and coagulation devices. The key design differences directly affect the ability of the devices to be cleaned and to maintain their physical and functional integrity after such cleaning. Specifically, reusable electrosurgical cutting and coagulation devices are made with metal components, which can withstand repeated exposure to harsh cleaning agents and can be disassembled for thorough cleaning and inspection. By contrast, single-use electrosurgical cutting and coagulation devices are made of molded plastic components and cannot be disassembled without destroying the device and cannot withstand exposure to harsh chemicals. The very features that compromise cleanability of the single-use devices are not present in the reusable devices. The existence of these reusable electrosurgical cutting and coagulation devices in no way diminishes the risk of infection associated with single-use electrosurgical cutting and coagulation devices because cleaning/sterilization techniques directed by the labeling of the reusable devices is only relevant to a device that can be disassembled and to components that can be exposed to harsh cleaning agents without damage. As such, the cleaning/sterilization techniques for the reusable devices cannot be applied to the single-use devices.

Question 5. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if a reprocessed electrosurgical cutting and coagulation device has been adequately cleaned and sterilized/disinfected?

No. We are not aware of any standards, performance tests, or guidance documents that would adequately assess the cleaning, disinfection, and/or sterilization of reprocessed electrosurgical cutting and coagulation devices.

Question 6. Are electrosurgical cutting and coagulation devices semi-critical devices?

No. As noted by FDA in the April 30, 2003 Federal Register Notice, electrosurgical cutting and coagulation devices are critical devices.

Having completed Flowchart #1, the RPS Guidance directs the conclusion that reprocessed electrosurgical cutting and coagulation devices present a high risk of infection.

(2) Evaluation of Risk of Inadequate Performance

Flowchart #2 in the RPS Guidance includes five questions designed to assess the risk of inadequate performance during reuse of a particular reprocessed single-use device.

Question 1. Does postmarket information suggest that using reprocessed electrosurgical cutting and coagulation devices may present an increased risk of injury when compared to use of a single-use device that has not been reprocessed?

Yes. The data summarized in Section B.2.b. above indicate that reprocessed electrosurgical cutting and coagulation devices can have bent shafts rendering insertion into a trocar more difficult. Such difficulty can then lead to damage of end effectors, plastic components, or protective coatings during surgery, as was seen in the studies. In addition, water soluble lubricants may be washed away during reprocessing making the devices more difficult to activate. Excessive clamp closing forces and damage to teeth and clamp pads can result in inability of the device to effect complete coagulation. Failure to adequately sharpen scissors may result in inability to cut tissue. Each of these defects can injure the patient or lengthen the procedure due to a need to replace the device. Perhaps most troubling is the finding that the protective sheaths on these devices can be replaced, damaged, or altered by reprocessing. This activity not only presents the potential for inadequate performance but also leaves both the patient and the healthcare provider exposed to electrical risk, including severe burns.

Having answered the first question “yes,” the RPS Guidance instructs us to find that electrosurgical cutting and coagulation devices present a high risk of inadequate performance. Despite this finding, we have responded to the additional Flowchart #2 questions to further demonstrate that electrosurgical cutting and coagulation devices present a high risk of inadequate performance even absent these postmarket data.

Question 2. Could failure of a reprocessed electrosurgical cutting and coagulation device cause death, serious injury, or permanent impairment?

Yes. Initial use and reprocessing can damage the devices’ dielectric coating or protective sheath, resulting in electrical discharge to unintended areas of the device. This, in turn, can result in electrical arcing with adjacent metal instruments and/or severe burns. In addition, failure of the devices to effect adequate coagulation could result in excessive bleeding at the site of intervention. Manual cleaning, chemical cleaning, and disinfecting agents can score plated surfaces and cause resistance between moving parts during use. In addition, bent shafts can impede insertion and removal of the device from a trocar and

result in damage to the device, including nicks or tears in the protective sheath and the unintended removal of end effectors.

Question 3. Do reprocessed electrosurgical cutting and coagulation devices contain any materials, coatings, or components that may be damaged or altered by a single use or by reprocessing and/or reesterilization/disinfection in such a way that the performance of the device may be adversely affected?

Yes. Many electrosurgical cutting and coagulation devices include lubricants which can be dissolved on washing/resterilization of the device. The lubricants play the important role of allowing device actuation at specified levels of force from the user. In addition, as noted above, the protective sheath may be damaged. Finally, polymers commonly used in electrosurgical cutting and coagulation devices may become brittle with repeated exposure to cleaning agents.

Question 4. 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 electrosurgical cutting and coagulation device has been altered due to reprocessing and use?

No. We are not aware of any relevant standards, performance tests, or guidance documents that would adequately determine if the performance of an electrosurgical cutting and coagulation device has been altered due to reprocessing and use.

Question 5. Can visual inspection determine if performance has been affected?

No. Damage to the protective sheath, lack of lubricant, and failure to adequately coagulate are not always evident on visual inspection.

Having completed Flowchart #2, the RPS Guidance directs us to conclude that reprocessed electrosurgical cutting and coagulation devices present a high risk of inadequate performance.

(3) Overall Risk

As can be seen from this exercise, reprocessed electrosurgical cutting and coagulation devices present both a high risk of infection and a high risk of inadequate performance. A “worksheet” included in Appendix 1 of the RPS Guidance directs us to find that the overall risk presented by reprocessing electrical cutting and coagulation devices is high if either of these are true.

d. Validation Data are Necessary to Demonstrate that Reprocessed Electrosurgical Cutting and Coagulation Devices Remain Substantially Equivalent to a Predicate Device.

In July 2003, FDA issued a guidance document regarding the validation data to be submitted under the MDUFMA requirements – a revised version of this guidance document was issued in June 2004.¹⁶ The guidance document provides specific recommendations regarding the validation data, noting that it interprets validation data as “broad in scope, including information about processing at the point of use to the completion of packaging and sterilization, and other post-process considerations.”¹⁷ FDA also stated that cleaning, sterilization, and functional performance validation of single-use devices includes aspects of both design validation and process validation.¹⁸ Review of such data is critical to a finding of substantial equivalence for reprocessed electrosurgical cutting and coagulation devices. The cleaning and performance failures noted in Section B.2.b and discussed in the RPS Guidance analysis demonstrate inadequate or nonexistent process and product validation, rendering these devices no longer substantially equivalent to predicate devices.

Inclusion of validation data in the 510(k)s for these devices would permit the FDA reviewer to review the reprocessing procedure and determine whether each step of that process is sufficient to achieve its cleaning/sterilization purpose without negatively affecting device integrity. Moreover, the reviewer would be aware of the maximum number of times a device is intended to undergo these steps and can consider whether successive reprocessing creates a device that is so weakened or damaged as not to be substantially equivalent to its predicate device. For instance, validation data would include

¹⁶ FDA, CDRH, Guidance for Industry and FDA Staff, “Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices” (June 1, 2004). The primary revisions to the guidance document related to the provision of more detail regarding the timeframe for FDA’s review of the validation data submissions and the actions FDA intends to take if it determines, after review of the MDUFMA-required validation data, that a reprocessed single-use device is not substantially equivalent to the predicate device.

¹⁷ Id. at 8.

¹⁸ Id. at 9.

information regarding cleaning agents that could be used to assess whether such agents would render plastic device components unacceptably brittle and susceptible to breakage upon recurrent exposure.

Moreover, validation data would demonstrate whether the cleaning endpoint includes more than mere visual inspection to assure that small lumens and crevices are sufficiently clean after reprocessing so that the devices can be sterilized. Validation data would also allow the FDA reviewer to determine whether limits for process residuals have been appropriately set.

Procedures for repair or replacement of the dielectric sheath would also be submitted along with engineering tests to demonstrate the device's continued suitability and substantial equivalence with this replaced component. Data from simulated use testing would provide information regarding activation forces needed and allow the reviewer to assess whether such forces are sufficiently comparable to those for the underlying device to render the devices substantially equivalent.

Finally, data regarding characterization and evaluation of packaging would permit the FDA reviewer to assess whether packaging is sufficient to protect the device from damage during shipment and to maintain sterility.

C. Conclusion

Reprocessing and reuse of electrosurgical cutting and coagulation devices presents a high risk to patients and should be included on List II. The requirement for cleaning, sterilization, and functional performance validation data for the maximum number of intended reuses will help assure that the reprocessed device remain substantially equivalent to the predicate devices throughout their intended period of use.

D. Environmental Impact

The action requested is subject to a categorical exemption from environmental assessment under 21 C.F.R. § 25.34.

E. Economic Impact

Pursuant to 21 C.F.R. § 10.30, HP&M will provide data concerning the economic impact of the relief requested should such information be requested by FDA.

F. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petitioner.

Respectfully submitted,



Josephine M. Torrente

Enclosures