There used to be one hospital in Utah that tried to meet re-manufacturing standards but never appears to have actually engaged in reprocessing operations because it could not meet FDA requirements. They appear to have purchase d a 510k and tried, but they couldn't meet the other requirements of being a medical device manufacturer.

AMDR's membership consists of Stryker, Vanguard (Germany), Medline Renewal, and Hygia. Sterilmed dropped out after J&J acquired them.

EP and surgical products are the most important. To-date, there are no EP ablation catheters reprocessed in the U.S. but a number of companies are working on them and there will be in the future.

J&J's Biosense Webster has worked hard to create obstacles to re-manufacturing. The OEMs like to make small unnecessary design changes to try to force the re-manufacturer to make new regulatory submissions which slows down the competitive effect of reprocessors in the marketplace.

In terms of the FDA process, the key differences vs. an OEM filing are related to cleaning and performance validation. The re-manufacturers have to include cleaning, sterilization, and performance testing validation to the agency on a premarket basis – information that is not required of OEMs on a premarket basis or at all. The re-manufacturer provides slightly different raw materials information. They don't provide information about the raw material suppliers. Instead, they use reverse engineering, among other techniques, to demonstrate they understand the material composition of the device.

Re-manufacturing has been regulated since 2000, so we have 15 years of history. In 2008, the General Accounting Office (GAO) did an evaluation of FDA's study and concluded, as did FDA, that re-manufactured SUDs were as safe and effective as new and noted no increase in adverse events due to reprocessing vs. OEM devices. OEMs will say that reprocessed devices fail more often and will do what I call the "dirty picture show," where they show examples of products that have failed as the results of reprocessing. These examples are never from purchased re-manufactured product from a regulated provider. They are always products that have been reprocessed in a hospital or inside a J&J lab. We completely agree that reprocessing isn't safe if it isn't done in a regulated way but, when done with a 510K-cleared method, it is safe, effective, and results in a device that is equivalent to the OEM device.

What the OEMs don't want to talk about is that there is a growing body of evidence that re-manufactured devices actually fail less frequently. Take a look at the *Loftus* study. Unlike the OEMs, re-manufacturers can't get away with batch testing. They have to test or inspect the functionality of every single unit. This means that quality is not only equivalent but can be even better than the OEM.

Because re-manufactured products are equivalent to the OEM product, informed consent isn't required in the U.S. or any other market.

I'll tell you an interesting story. Boston Scientific/Microvasive used to offer the same biopsy forceps for one price as a re-useable and at another price as an SUD. The product was exactly the same. Everyone knows that many devices can be re-used but the OEM is the one who gets to decide and they are incentivized to designate a product as single use.

Tracking and labeling are important. We don't use GS1 compliant systems yet in the U.S. but every device has a bar code and is tracked. This is an FDA requirement. It helps to track the number of times a device has been used and it also helps the re-manufacturer ensure that there is a closed loop – i.e.,

that only one company is re-manufacturing the same device. If the re-manufacturer collects a device with another re-manufacturer's bar code, it would be rejected. In terms of labeling, devices are designated as being for "single-use" and the re-manufacturer's name is listed as well as the information about the original device. The label doesn't have to include the number of times the device has been re-used but the re-manufacturer does have to track this in their system.

1. Re-manufacturing has a long history in the U.S. and Germany and will begin in the UK and EU later this year. As you know, reimbursement in all of these markets is the same for both re-manufactured and OEM devices. The reason for this is that the devices are viewed as equivalent.
2. the UK doesn't plan to initially allow the re-manufacturing of Class I devices. I think they will eventually change their minds on this as the EU plans to allow Class I re-manufacturing. The reason the UK has decided not to is that they don't currently have much significant oversight for any for Class I devices and they don't think the savings will be significant enough to warrant one – for now. In the U.S., Class I devices don't require pre-market authorization; however, manufacturers do have QMS-like requirements (Quality System Regulation/Good Manufacturing Practices). Internationally, this is much akin to ISO 13485 compliance.
3. Canada has issued a memo allowing re-manufacturing under existing medical device requirements there. Australia hasn't issued a guidance document yet but will allow re-manufacturing based on existing regulations.
4. In all markets that I am aware, the reimbursement is the same for re-manufactured and new devices. This is important, especially for EP, because it improves the profitability of these procedures which historically haven't been very profitable because of the time they require and the high cost of devices.
5. Stryker is the dominant player and probably has close to 70% of the market – they acquired a number of companies and the industry is fairly consolidated with only a few major players. Stryker does Class I and Class II products. Sterilmed (acquired by J&J) used to be #2 but has likely fallen to #3. J&J doesn't really support the business and has allowed it to decline. For them, re-manufacturing is being used as a way to fend-off other re-manufacturers. They offer re-manufactured products but then they don't actually provide them. Because the price of the new product is so much higher than the price for the re-manufactured product, the sales representative has no incentive to offer the cheaper product. Sterilmed is now probably #3 and I'd put Medline Renewal at #2 and then Hygia at #4, but they mainly reprocess Class I devices. Covidien (acquired by Medtronic) also offers re-manufactured Nellcor pulse oximeter sensors but this business is pretty small and it will be interesting to see if Medtronic supports it now post merger with Covidien.
6. In terms of the FDA process, the key differences vs. an OEM filing are related to cleaning and performance validation. The re-manufacturers have to include cleaning, sterilization, and performance testing validation to the agency on a premarket basis – information that is not required of OEMs on a premarket basis or at all. The re-manufacturer provides slightly different raw materials information. They don't provide information about the raw material suppliers. Instead, they use reverse engineering, among other techniques, to demonstrate they understand the material composition of the device.

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米国１－１－３　Stryker Sustainability Solutions

Bill Scott, Senior director marketing
Stryker Sustainability Solutions
March 2, 2016
09:00 a.m. - 09:45 a.m.

Remanufacturing has been happening well before 2000 when it had started to be regulated. The industry is now in its third generation. The first generation is prior to the year 2000 when medical device reprocessing was an unregulated practice. The industry was very fragmented with many small companies reprocessing for hospitals all over the United States. The second generation of this industry is following the year 2000 when the practice of remanufacturing had become regulated by the FDA, this also the shift from medical device reprocessing to remanufacturing. During this time many of the smaller medical device repressors had begun to merge through acquisitions and partnerships and legitimized fully regulated remanufacturing companies had begun to operate in the United States. The current generation (third) of medical device reprocessing/remanufacturing is when OEM companies had begun moving into the remanufacturing industry through acquisitions and investment into the industry. The OEMs moving into this space has helped further legitimize the industry and has helped in giving the remanufacturing industry more credibility and has helped the hospitals understand that remanufactured products are of the same quality as OEMs because the OEMs are now remanufacturing them. A few examples of OEMs acquiring remanufacturing companies are Stryker acquiring Ascent, Medline acquiring Medesiss, J&J acquiring Sterilmed.

The US has a total of about 20 remanufacturing companies today of which there are 5 large remanufacturing companies, these five are most of the market share, and is dominated by OEMs. So today OEM companies dominate the remanufacturing industry. Additionally the FDA has just over 100 remanufacturing companies registered in their database.

The topic of product quality and equivalence of the products is very critical for our industry. SSS does not batch test the products, what we do is full performance testing for all of the products. Additionally the GAO has produced a report and gone on to state that reprocessed/remanufactured devices perform in the same exact way as OEM, and have significant cost benefits.

At SSS we categorize the areas where we deliver value as

1. Environmentally friendly, for many hospitals we divert about 100,000 lbs of waste annually.
2. Cost containment, for a 400 bed hospital we typically save about 500,000 USD annually just in saving from remanufacturing.
3. Improved patient care because remanufacturing is safer then in hospital reprocessing.

In 2015 we have saved our customers a total of 262 million USD, this saving does not include the savings from OEM prices going down as a result of the competition that we bring to the market and the cost savings we provide from our collections programs. Additionally we have diverted 12.3 million lbs of waste from the landfills. Our goal for 2016 is to grow each of these numbers by 19%.

We currently have three major product categories. The first is our surgical products, which are mainly directed energy devices (laproscopic), ultrasonic scalpels. Ultrasonic scalpels are very big cost savers for the hospitals. The second group is our vascular products group, which is mainly EP catheters, ultrasound catheters, and cables for the catheters. The last major product group that we have is our noninvasive products; this group is mostly made up of compression sleeves, DVT sleeves, and pulse oximeters.

SSS currently is not does not reprocess Stryker product. In our customer feedback we have heard that hospitals think that it may be important that the OEM product and the remanufactured product be different. Many hospitals feel that there is a conflict of interest if the remanufacture is remanufacturing the same product their parent company sells because it creates a conflict of interest. Recently many hospitals feels as if some companies are collecting all of their devices but are being sold only brand new products.

The market has evolved and changed over the years. The market has also grown significantly. 2011 the US was a 196 million USD market; last year in 2015 it was 315 million USD. As I have mentioned previously in 2011 it was just reprocessors, today the market is dominated by OEMs. I have heard that J&J sales representatives are now selling remanufactured products as a result of the acquisition. But in most situations the sales representative will sell the brand new device because they are incentivized to do so. This has affected the sales of Sterilmed, prior to the acquisition the company had been experiencing revenue growth, and following the acquisition the company has had declining sales. They have also since the acquisition left the remanufacturing industry association (AMDR). OEMs will often put in their sales contract with hospitals that a hospital is only permitted to purchase a certain percentage or amount of remanufactured products annually.

Medtronic has also entered the space; their Ligasure products are their main products. Hospitals have told us that they collect these products from the hospitals and offer rebates for new products. I imagine this is a tactic to dry up the supply of the used devices.

To me it seems as if all remanufacturing companies need an OEM partner in order to operate in the US today because it gives the companies credibility.

We often hear from SterilMed that they are better at reprocessing a J&J device because they have access to the information that we would have to use reverse engineering to get. But we will launch a J&J product before SterilMed. We are able to do this because we have significant experience in this space, and we are able to validate all of our processes that go into remanufacturing.

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5. To me it seems as if all remanufacturing companies need an OEM partner in order to operate in the US today because it gives the companies credibility.

米国１－１－４　Mayo Clinic Phoenix

Donanda Reimer, M.S.N., R.N.
Manager Clinical Support Services
Surgical Services
Supply Chain Management
Mayo Clinic Phoenix, Arizona
March 3, 2016
09:00 a.m. - 10:00a.m.

I have been here since the very beginning of the hospital, and reprocessing has had a very long history at this hospital. This hospital currently has 268 beds and we are expanding the hospital again in the near future. We generally run at capacity or very close to capacity during the winter months, and in the summer when it is very hot we are running at about 5% less.

Reprocessing/remanufacturing has had a very long history in this hospital and it has become a larger part of our savings as time has gone on. In the beginning we only did surgical devices and other very simple devices like pulse oximeters, and dvt sleeves.

In the beginning we had some issues with some doctors/nurses not using the remanufactured products. It took a about a year to train the staff to prioritize these products over OEM. Currently we are mainly using the surgical devices from Stryker, and the devices that we use in the cath lab such as EP catheters. EP catheters are a larger savings for our hospital because the devices cost so much brand new.

We have very low fail rates for the remanufactured devices I would guess under 1%, and the doctors that use the EP catheters do not notice a difference in its performance or in its feel. In fact we have had larger fail rates with OEM devices. Currently we are not remanufacturing ablation catheters but I do tell our Stryker representative to please add more products to the portfolio. I would say that our hospital has savings of about 400,000USD from using these devices. This does not include the cost savings from the OEM pricing going down.

We have considered passing the savings to our patients in the past and this has come up. But we are not doing so. We believe that the savings from the remanufactured devices could be used to hire another nurse, or to purchase another piece of equipment for the hospital instead. The savings that we have here is reinvested into the hospital, which benefits the patients.

We do not do informed consent here for the use of remanufactured devices. We feel that informed consent is used for situations such as clinical trials. We are not conducting studies on the patient; we are delivering the same care to the patient with pretty much the same device. To guarantee to ourselves and to the patients that we are delivering the same level of quality health care with these devices, when we adopt a new remanufactured device for use in our hospital we conduct our own clinical trial for the new remanufactured device. This trial period for the device typically lasts between two and four weeks. The equivalence of the device to the OEM is guaranteed by Stryker but our doctors will test to see if they feel the same and perform the same way. Also this the time when we can see how comfortable the doctor is with the device. For this we will purchase testing samples of the new product from Stryker. In the pas we have never really had a problem with any of the remanufactured devices.

Our relationship with the OEMs has always been very strong. But there have been situations where the OEM tries to discourage remanufacturing. One case that I remember very specifically is that an OEM tried to void warranties on our consoles because we had been purchasing and using remanufactured devices on them. This led to a legal battle, which we won. The courts decided that the OEM was not allowed to void warranties on our capital equipment as a result of purchasing remanufactured products.

Collections have been a very big cost savings. Currently we are paying 50 cents a pound to dispose of our medical waste, and the collections program helps to bring that cost down. In the early days we would have to sort out all of the medical waste and put into separate bins and then have the waste management people come in and take it away. Now we have the collections bins from Stryker all over the hospital, primarily in the OR, and in the cath labs where most of the

collections are happening, every week or so a bunch of collections bins from Stryker comes into our facility, and they are brought up into the hospital. We also have another type of bin where things like EP catheters are placed in, inside and outside of the cath labs. Additionally the Stryker rep is here all of the time to consistently monitor the collections and to check up on everything. Currently we are emptying the bins about once a week. Because we no longer have to deal with sorting the waste anymore the environment has become simpler and safer for my staff. But this requires continuous education and reeducation.

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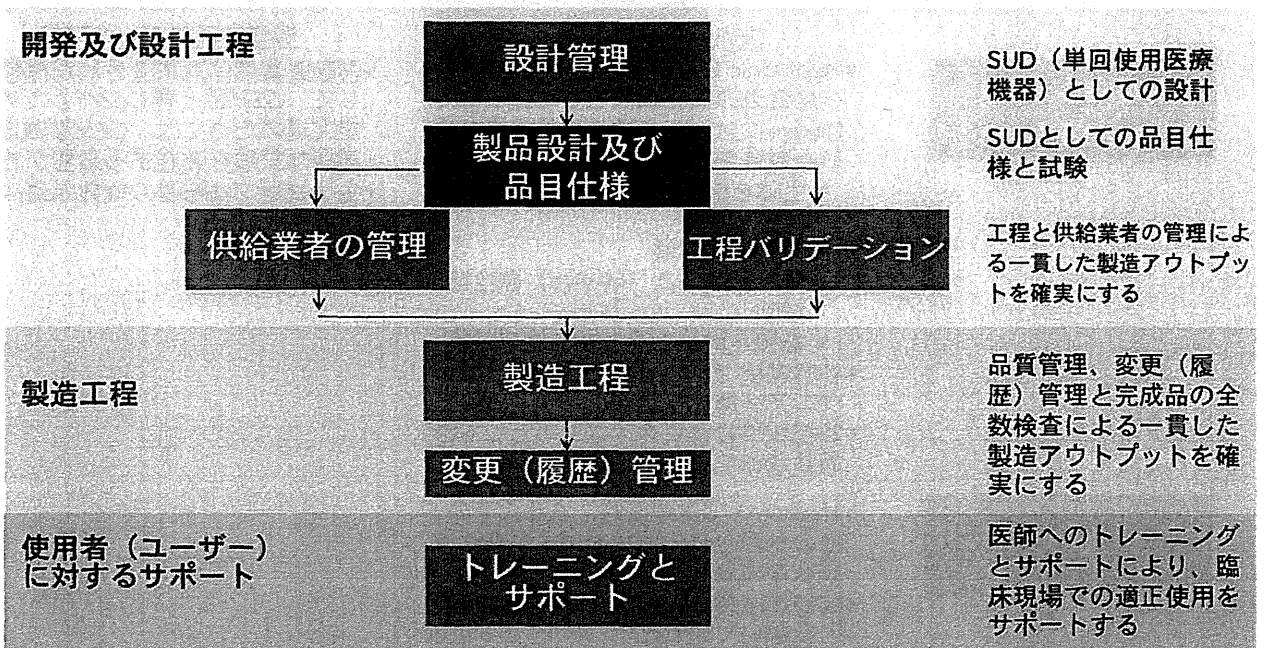
8.

JAPAN MINISTRY OF HEALTH, LABOR AND WELFARE
再製造に対する検討事項

Medtronic
Further, Together

品質管理のプロセス
各工程においてLIGASURE™の品質を確立

「医療機器は数多くの構成品やその複雑度から製造業者による完成品の検査や試験のみでは適切性を確保可能とは言えず・・・
FDAは、品質は適切な品質システムの運用に従い設計及び組み立てられることにより確立されると信じる[1]。」



United States FDA. Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, October 7, 1996.

SUD製品の設計管理
厳格な管理により製品要求事項への合致を確実にする

SUDの設計管理では、機器の単回使用のみでの製品要求事項への合致を確実にしている。詳細な品目仕様により機器の性能上の要求事項への合致を確実にしている。

	OEM事業者の手法	機器の再製造との関係
設計管理	▪臨床上の要求項目が設計要求事項のインプットとなる。 ▪品目仕様は単回使用品として設計されており 　▪単回使用としてのみ信頼性を確保している。 　▪機器は、複数回にわたる使用時に、清浄度や耐久性が確保できるよう設計されていない	▪機器は複数回にわたる使用を考慮して設計されていない。 ▪多くのSUDの外科系機器は間隙、鋭角な部品断面やその他の特殊な形状・構造を有しており、使用後の完全な洗浄が困難となっている。
品目仕様	▪最適な性能は力学的、温度的、さらに切断性能の厳格な管理による実現される。品目仕様はこれらの詳細な要求事項に合致するよう開発・設定されている。	▪再製造時の「リバース・エンジニアリング」ではOEM業者が設定した品目仕様等の情報が得られないため、機器が最適な性能を発揮するための特性や公差等の情報が得られていない可能性。

品目仕様に基づいた試験
機器が要求事項に合致していることを確実にする

SUDの性能上の要求事項への合致を確実にするために、設計工程では広範な試験を実施する。試験には特殊な治工具やソフトウエアが必要になる。

	OEM事業者の手法	機器の再製造との関係
生体組織を用いた試験	▪Medtronicでは機器の性能要求事項への合致の検証試験としてEnergy Deviceに対して各種の生体組織を用いた試験を実施している。 　▪ 生体組織を用いた非臨床での止血性能試験 　▪ 加熱特性試験 　▪ 動物を用いた（in-vivo）急性期試験 　▪ 動物を用いた慢性期の生存試験 ▪各種試験では特殊な治工具やソフトウエアを用いている。 ▪各種試験の合否判定はSUDとしての品目仕様に由来している。	▪再製造業者は再製造された機器に対して、OEM品と同じレベルでの性能実現のためには、OEM事業者と同様な試験を実施する必要がある。 ▪各種試験では機器の複数回使用を想定していない。
機械的さらにその他の分野の試験	▪Medtronicでは機械的、さらにその他の分野からの要求事項に由来する試験を実施している。 ▪試験には特殊な治工具やソフトウエアを用いている。 ▪各種試験の合否判定はSUDとしての品目仕様に由来している。	

供給業者の管理
供給業者及び品質システムの認定と供給する部品の承認

全ての供給業者は認定され、供給する部品の品質確保のための仕様情報が定められる。

	OEM事業者の手法	機器の再製造との関係
原材料・部品供給業者の認定	▪OEM事業者の品質システムに基づいて供給業者を評価・認定する。	▪医療機関にて使用された機器は回収用のゴミ箱に入れられた後に再製造業者に出荷されているが、供給業者としての認定は受けていない。
原材料・部品の品目仕様への反映	▪必要な品目仕様情報を共有業者と共有する。 ▪製造された納入部品は品目仕様に従い厳格な検査を実施し、承認を受ける。	▪製品の最善の性能を発揮するための原材料及び部品の仕様や公差情報が得られないまま（代替される）部品が供給される。 ▪リバースエンジニアリングにより得られる原材料情報は（分析）業者等により異なるため、原材料情報にばらつきが発生する。
供給業者への監査	▪供給業者に対する定期的な監査を実施し、品質管理システムへの遵守を確実にする。	▪使用済みの機器は医療機関により供給される。

工程バリデーション
工程管理により一貫した製造アウトプットを確実にする

工程バリデーションにより、仕様に合致した製品を一貫して製造する「製造工程」を確保する。

	OEM事業者の手法	機器の再製造との関係
工程バリデーション	▪全ての製造工程は試験とそれに基づいたバリデーションを実施し、製造される機器の性能が常に品目仕様に合致していることを確実にしている。 ▪バリデーションには数多くの試験並びにそれらに基づく工程（適格性の検証）が必要となる。	▪再製造業者は（OEM事業者が定めた）品目仕様や公差といった情報を入手できない。 ▪再製造業者が実施する最終試験は機器の性能と安全性を担保するのに適切とは言い難い。

製造工程
各種試験と品質管理工程

Medtronicでは事前に設定された公差と全数検査に基づいて品目仕様上重要な品質確保項目を担保している。

	OEM事業者の手法	機器の再製造との関係
製造工程	▪多くの製造工程では厳格な公差管理による正確性が要求されている。 ▪製造工程では性能を発揮するために外見上では確認することのできない多くの工程があり、製造時に用いる潤滑性材料はその一例である。 ▪機器の筐体は厳格な公差管理によるレーザー溶着工程等を用いて接合されている。	▪再製造業者は品目仕様や公差情報を知り得る立場にない。 ▪機器の洗浄工程により潤滑性材料といった外見上確認できない（再製造業者が知りえない）ものは洗い流される可能性があり、これは他の材料でも同様であろう。 ▪溶着部分の分解により筐体の破損の恐れがあり、再製造品ではOEM品と同様の正確な溶着が確保できない。
試験	▪品質に重大な影響を与える製品機能については全数検査を実施している。 　▪特定の機能については2回にわたる全数検査を実施している（200%）。 　▪試験は装置により自動化されたものもあれば、作業者によるマニュアル試験もある。	▪再製造業者は一貫した製品性能の実現のための試験すべき機能や仕様を知りうる立場にない。 ▪再製造業者はOEM事業者が用いている試験装置や作業者の教育訓練内容を知り得る立場にない。

変更管理
全ての変更は文書化され、検証され、さらに試験されている

全ての変更について履歴を管理し、検証試験を実施している。再製造業者はOEM事業者における変更を知る立場にはない。

原材料や部品の供給停止や製品改善に伴い、変更は往々にして発生する。

	OEM事業者の手法	機器の再製造との関係
変更に対する試験、確認並びに検証	▪変更は全て文書化され、関連する複数の部門により確認される。 ▪変更を検討する際には、その影響や関連を理解するために試験を実施する。	▪再製造業者ではOEM事業者における変更を知り得る立場にない。 ▪OEM事業者による工程、原材料並びに部品情報が変更された場合には、変更前と同様にOEM製品と同様な製品の製造はできない。

トレーニング及びサポート
医学専門家へのサポートにより市場での適正使用を確保

医学専門家に対する製品トレーニングといったサポートや、顧客サポート部門による製品の市場での効果的な使用のサポート。

サポート

トレーニング

OEM事業者の手法

- Medtronicでは文書化された手順に従い、不具合情報の収集と分析を実施している。

- Medtronicでは術者や看護師に対する広範なトレーニングを提供し、適切な市場での製品使用をサポートしている。
  - 技術的な認定制度を設けたトレーニング
  - 学術情報
  - 手技のトレーニング

機器の再製造との関係

- OEM事業者は再製造を行っていないため、再製造品に対する不具合情報について分析する立場にない。

まとめ

- LigaSure™ は単回使用を前提に設計されている。
- Medtronic は厳格な製品開発、試験、工程バリデーション、変更管理並びに供給業者に対するバリデーションを実施し、品質と（製品性能）の一貫性を担保している。
- 当社が設定した品目仕様は当社の重要な管理情報として扱われている。

The Medtronic Mission, Tenet 3

To strive without reserve for the greatest possible *reliability and quality* in our products and to be the unsurpassed standard of comparison. To be recognized as a company of *dedication, honesty, integrity and service.*

脚注

1. United States Food and Drug Administration. Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, October 7, 1996.

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.

Draft released for comment on February 8, 2000

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.