Summary of Safety and Effectiveness for the Reprocessed Electrosurgical Instrument(s)

submitted by

SISS Inc. (d.b.a. MediSISS)
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Contact Person: Mary Ann Barker
Device Trade Names: Reprocessed Electrosurgical Instruments and Accessories
Common Names: Reprocessed Electrosurgical Instruments and Accessories
Classification Names: Electrosurgical, Cutting and Coagulation and Accessories
Classification and Code: CFR §878.4400, GEI

Identification of a Legally Marketed Predicate Device

The SISS Inc. (d.b.a. MediSISS) Reprocessed Electrosurgical Instruments are substantially equivalent to the electrosurgical instruments manufactured by:

Ethicon
U.S.Surgical

These devices are legally marketed and distributed pursuant to 510(k)'s K984240, K951589, and K934784 and the counterpart devices from the original manufacturers.

They are also similar to the reprocessed electrosurgical instruments and accessories reprocessed by Alliance Corporation and legally marketed and distributed pursuant to, K012625. Likewise, SterilMed, Inc. *Reprocessed Laparoscopic Electric Instruments*: - 510(k) K012598; and Vanguard Medical Concepts, Inc *Vanguard Reprocessed Endoscopic Instruments*, 510(k) K012700.

Device Description

Reprocessed Electrosurgical Instruments may consist of hand-manipulated devices with electrocautery capability and with or without rotation capability.

The distal end of the Ethicon device consists of a scissor distal end configuration. The U.S Surgical device consists of a dissector distal end configuration. The devices are designed to be inserted through an appropriately sized trocar sleeve or cannula. The end-

effectors are operated by the handpiece handle. The ring handles may be designed to be suppressed and released to activate the instruments end-effector.

The device's insulated shaft may be designed to (depending on the device model and type) be rotated (up to 360°) either direction (using a knob on the handle.)

Intended Use

The SISS Inc. (d.b.a. MediSISS) Reprocessed electrosurgical instruments have applications in a variety of minimally invasive surgical procedures to manipulate and manage internal soft tissue by grasping, cutting, and/or to facilitate coagulation, transection, resection, mobilization, and dissections of tissue.

Functional and Safety Testing

Reprocessed Instrument samples underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and packaging and sterilization procedures. In addition, the manufacturing process includes visual and functional testing of all products produced.

Summary of Technological Characteristics

The intended use and technological features of the reprocessed devices do not differ from the legally marketed predicate device(s). Both the reprocessed devices(s) and the predicate device(s) have the same materials and product design. There are no changes to the claims, intended use, clinical applications, patient populations, performance specifications, or methods of operation. The technological characteristics of the reprocessed electrosurgical devices are the same as those of the legally marketed predicate devices. The technological characteristics of the reprocessed electrosurgical device(s) are the same as those of the legally marketed predicate devices. In addition the MediSISS™ manufacturing process includes 100 % visual and mechanical testing of all products prior to packaging, labeling, and sterilization.

Summary of Performance Data

Performance data demonstrates that the Reprocessed Instruments perform as originally intended.

The SISS Inc. (d.b.a. MediSISS) Reprocessed Electrosurgical Instruments comply with the following standards, practices, and guidance's:

- ANSI/AAMI/ISO 11135-1994. *Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization*
- ANSI/AAMI/ISO 10993-7:1995, *Biological Evaluation of Medical Devices Part 7: Ethylene oxide sterilization residuals*
- ANSI/AAMI/ISO 10993-1: 1997 (1999 Edition). *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.*

MediSISS™ Reprocessed Electrosurgical Instruments undergo mechanical testing to demonstrate that the parts do not change in function. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging.

Cleaning, sterilization, and packaging validations, functional/performance testing, (product certification,) and (biocompatibility) testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

Representative samples of reprocessed electrosurgical instruments underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Substantial equivalence has been established with respect to intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, standards, and other applicable characteristics. The SISS Inc. (d.b.a. MediSISS) Reprocessed Electrosurgical Instruments are therefore substantially equivalent to the identified predicate devices.

Conclusion

Since the Reprocessed Electrosurgical Instruments meet the requirements of the stated standards and embody technological characteristics substantially equivalent to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The Reprocessed Electrosurgical Instruments will be reprocessed per specifications and QSR good manufacturing practices that ensure the device is safe and effective for its intended use.

The reprocessed device have the:

- same intended use as the predicate; and
- has the same technological characteristics as the predicate device
- and can meet the same performance standards as the predicates

In accordance with the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this Premarket notification, SISS Inc. (d.b.a. MediSISS) concludes that the modified devices (Reprocessed Electrosurgical Instruments) are safe, effective and substantially equivalent to the predicate devices described herein.

Based on the information provided herein, the 510(k) "Substantial Equivalence" Decision Making Process Chart, and the FDA "510(k) Guidance Document for General Surgical Electrosurgical Devices" 5/10/95, we conclude that the SISS Inc. (d.b.a. MediSISS) reprocessed electrosurgical instruments are substantially equivalent to the predicate devices under the Federal Food and Drug, and Cosmetic Act.

This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 4 2003

Surgical Instruments Service and Savings, Inc.
c/o Mr. Marc M. Mouser
Project Engineer, Medical Devices
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
Camas, Washington 98607-8542

Re: K031869
Trade/Device Name: SISS Inc. Reprocessed Electrosurgical Instruments and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 10, 2003
Received: December 12, 2003

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K031869

Device Name: SISS Inc. (d.b.a. MediSISS) Reprocessed Electrosurgical Instruments and Accessories.

Indications for Use:

The SISS Inc. (d.b.a. MediSISS) Reprocessed electrosurgical instruments have applications in a variety of minimally invasive surgical procedures to manipulate and manage internal soft tissue by grasping, cutting, and/or to facilitate coagulation, transection, resection, mobilization, and dissections of tissue.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

510(k) Number K031869