MEDISISS

JAN - 7 2014

510(k) 124033
MEDISISS Reprocessed Harmonic FOCUS Curved Shears FCS9

K124033

Section 5: 510(K) Summary

Submitter/ Owner	MEDISISS 2747 SW 6th St. Redmond, OR 97756
Contact Name	Brandi Panteleon Director of Product Development P: 541-923-3310 F: 541-923-3375 E: bpanteleon@medisiss.com
Date Prepared	December 26, 2012
Device Names	Proprietary Name: MEDISISS Reprocessed Harmonic FOCUS Curved Shears FCS9 Common Name: scalpel, ultrasonic, reprocessed
Classification	Scalpel, Ultrasonic, Reprocessed, Unclassified, product code NLQ
Predicate Devices	K100597 Ethicon Endo-Surgery Harmonic FOCUS Shears K063192 Ethicon Endo-Surgery Harmonic FOCUS Shears
Device Description	MEDISISS Reprocessed Harmonic FOCUS Curved Shears FCS9 (originally manufactured by Ethicon Endo-Surgery). Following clinical use, the instruments are cleaned, refurbished, tested, inspected, packaged, sterilized with ethylene oxide and returned to the user facility by MEDISISS for an additional clinical use.
Intended Use	The MEDISISS Reprocessed Harmonic FOCUS Curved Shears FCS9 is indicated for soft-tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to, or substitute for, electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ear, nose and throat [ENT]), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space), and other open procedures.
Technological Characteristics	The technological characteristics of the subject device are substantially equivalent to the predicate device listed in this submission. The subject device has the same functionality and indications as the predicate device.

Performance Testing	The functional characteristics of the subject device have been evaluated and found to be substantially equivalent to the predicate device based on the below tests:
	• grasping/pull force;
	• cutting effectiveness /functionality;
	• drop test;
	• device integrity;
	• cutting/coagulation evaluation for a prolonged period of time;
	• thermal analysis characterization;
	• tissue sticking;
	• simulated use;
	• IEC 60601-1;
	• cleaning;
	  o protein, carbohydrate, hemoglobin, and endotoxins;
	• biocompatibility;
	  o cytotoxicity, sensitization, irritation, and acute systemic toxicity;
	• performance qualification;
	• sterilization and
	• stability.

Conclusion	Based on a comparison of the Indications for Use, technological characteristics, and performance data to the predicate device, the MEDISISS Reprocessed Harmonic FOCUS Curved Shears FCS9 are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

MEDISISS
Ms. Brandi Panteleon
Director, Product Development
2747 Southwest 6th Street
Redmond, Oregon 97756

January 7, 2014

Re: K124033
Trade/Device Name: MEDISISS Reprocessed Harmonic FOCUS Curved Shears FCS9
Regulatory Class: Unclassified
Product Code: NLQ
Dated: December 20, 2013
Received: December 26, 2013

Dear Ms. Panteleon:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use

510(k) Number: ~~TBD~~ K124033

Device Name: MEDISISS Reprocessed Harmonic FOCUS Curved Shears FCS9

Indications for Use:

The MEDISISS Reprocessed Harmonic FOCUS Curved Shears FCS9 is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space), and other open procedures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056
Date: 2014.01.03 15:02:18 -05'00'

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K124033