



Food and Drug Administration
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October 26, 2016

Medos International SARL
Ms. Jennifer Siu
Regulatory Affairs Specialist
Chemin-Blanc 38
2400 LeLocle, Switzerland

Re: K162469

Trade/Device Name: CODMAN VersaTru Standard Disposable Non-Stick Bipolar Forceps,
CODMAN VersaTru Slim Disposable Non-Stick Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 1, 2016
Received: September 2, 2016

Dear Ms. Siu:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

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

Enclosure

Indications for Use

510(k) Number (if known)

K162469

Device Name

CODMAN VersaTru Standard Disposable Non-Stick Bipolar Forceps
CODMAN VersaTru Slim Disposable Non-Stick Bipolar Forceps

Indications for Use (Describe)

CODMAN VersaTru Standard Disposable Non-Stick Bipolar Forceps and CODMAN VersaTru Slim Disposable Non-Stick Bipolar Forceps are intended for use in electrosurgery for coagulation of tissue.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date of Submission: September 1, 2016

II. Device

Device Proprietary Name	CODMAN VersaTru™ Disposable Non-Stick Bipolar Forceps
Common Name	Disposable Bipolar Forceps
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400)
Regulatory Classification	II
Product Code	GEI

III. Predicate Device

The predicate device for this submission is the Synergetics™ Disposable Spetzler™ Malis® Standard Bipolar Forceps (K121426), which was cleared on July 10, 2012.

IV. Device Description

The CODMAN VersaTru Disposable Non-Stick Bipolar Forceps (VersaTru Bipolar Forceps) are single use, disposable, sterile electrosurgical devices, for use in electrosurgery for the coagulation of tissue. The forceps are part of an electrosurgical system consisting of an electrosurgical bipolar generator and bipolar cord attached to the proximal end of the forceps, to provide power and deliver electrical current from the generator to the distal tips of the forceps.

V. Indications for Use

CODMAN VersaTru Disposable Non-Stick Bipolar Forceps are intended for use in electrosurgery for coagulation of tissue.

**VI.
Comparison to
Predicate
Device**

The VersaTru Bipolar Forceps is substantially equivalent to the predicate device, the Synergetics Disposable Spetzler Malis Standard Bipolar Forceps. The subject device has the same indications for use and clinical utility, and similar design principles, materials, and packaging as the predicate device. The table below provides a comparison between the subject device and the predicate device.

Comparison of the Predicate and Subject Device		
	Predicate Device: Synergetics Disposable Spetzler Malis Standard Bipolar Forceps (K121426)	Subject Device: CODMAN VersaTru Disposable Non-Stick Bipolar Forceps (This Submission)
FDA Product Code	GEI	Same as predicate
Classification	Class II - 21 CFR 878.4400	Same as predicate
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories	Same as predicate
Indications for Use	Sterile, single use, for use in electrosurgery for coagulation of tissue	Intended for use in electrosurgery for coagulation of tissue
Single Use	Yes	Same as predicate
Forceps Design	Bayonet Style	Same as predicate
Product Line	Standard	Standard Slim
Forceps Length	7", 8", 9"	Standard: 7", 8", 9" Slim: 8", 9"
Forceps Tip Size	0.5 mm, 1.0 mm, 1.5 mm	Same as predicate
Forceps Color	Yellow	Blue
Forceps Tips	Plated aluminum	Plated aluminum
Coating	Polyvinylidene fluoride	Polyamide
Electrical Safety Testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Same as predicate
Packaging Materials (Sterile Barrier)	PETG tray Tyvek lid	Same as predicate
Packaging Unit	5 units per box	1 unit per box
Sterility Assurance Level (SAL)	10 ⁻⁶	Same as predicate
Sterilization Method	Ethylene oxide	Gamma irradiation
Shelf Life	5 years	1 year

**VII.
Performance
Data**

The following performance data has been provided in support of the substantial equivalence determination. All testing was performed on final sterile devices unless otherwise specified.

Bench Testing

Performance bench testing was conducted in alignment with FDA's guidance

Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery issued August 15, 2016 and internal requirements.

Performance Bench Test Results	
Test	Conclusion
Lesion Size	Pass
Resistivity	Pass
Weight Test	Pass
Non-Stick Test	Pass
Thermal Effects Lesion Study	Pass
Mechanical Test	Pass
Dimensional Verification	Pass
Physical Characterization	Pass
Functional Testing (after transit)	Pass
Ergonomics Validation	Pass

Electromagnetic Compatibility/ Electrical Safety Testing

EMC and electrical safety testing were conducted in accordance with IEC 60601-1-2:2014 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*, IEC 60601-1:2005/A1:2012 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*, and IEC 60601-2-2:2009/C1:2014 *Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*. The VersaTru Bipolar Forceps passed all EMC and electrical safety testing.

Sterilization

The VersaTru Bipolar Forceps is sterilized using a validated gamma irradiation sterilization cycle. The sterilization cycle has been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11137-1:2006/Amd1:2013 and ISO 11137-2:2013, *Sterilization of health care products – Radiation*.

Shelf-Life Testing

Shelf-life testing was conducted in accordance with FDA's guidance document *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* issued August 15, 2016 and internal requirements. VersaTru Bipolar Forceps was subjected to accelerated aging. The aging studies established that the device and packaging remain functional and maintain sterility for up to 1 year.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993-1:2009/AC:2010, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, and FDA's guidance documents, *Use of International Standard ISO 10993-1, "Biological*

evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” issued June 16, 2016 and Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery issued August 15, 2016.

Biocompatibility Test Results	
Test	Conclusion
Cytotoxicity Study using the ISO Elution Method (1X MEM) ISO 10993-5	PASS Non-cytotoxic
ISO Guinea Pig Maximization Sensitization Test ISO 10993-10	PASS Non-sensitizing
ISO Intracutaneous Study in Rabbits ISO 10993-10	PASS Non-irritating
ISO Systemic Toxicity Study in Mice ISO 10993-11	PASS Non-toxic
USP Rabbit Pyrogen Study, Material Mediated ISO 10993-11 General Chapter <151>	PASS Non-pyrogenic
ASTM Hemolysis Study (Extract Only) ISO 10993-4 ASTM F756	PASS Non-hemolytic
Chemical Characterization of Extractables ISO 10993-18	PASS
Toxicology Risk Assessment ISO 10993-17	PASS

Animal Studies

No animal studies were performed as appropriate verification and validation of the new device was achieved based on the comparison to the predicate device and from the results of the bench testing, biocompatibility evaluation, and electrical/safety testing.

Clinical Studies

No clinical studies were performed as appropriate verification and validation of the new device was achieved based on the comparison to the predicate device and from the results of the bench testing, biocompatibility evaluation, and electrical/safety testing.

VIII. Conclusion

Based upon the intended use, design, function, materials, comparison to the predicate device, and testing conducted, it is concluded that the subject device, VersaTru Bipolar Forceps, is substantially equivalent to the predicate device, Synergetics Disposable Spetzler Malis Standard Bipolar Forceps (K121426), and therefore does not raise different issues of safety and effectiveness.
