DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 1, 2016

Medos International SARL
Ms. Megan Palumbo
Senior Regulatory Affairs Specialist
Chemin-blanc 38
2400 Le Locle, Switzerland

Re: K163106
Trade/Device Name: Codman Integrated Bipolar Cord and Tubing Set
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 4, 2016
Received: November 7, 2016

Dear Ms. Palumbo:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163106

Device Name
CODMAN Integrated Bipolar Cord and Tubing Set

Indications for Use *(Describe)*
The CODMAN Integrated Bipolar Cord and Tubing Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation.

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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Section 5 – 510(k) Summary

I. Submitter

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Establishment Registration Number: 1226348

On behalf of:
Medos International SARL
Chemin-Blanc 38
2400 LeLocle, Switzerland

Establishment Registration Number: 3008114965

Contact: Megan Palumbo
Phone: (508) 828-3571
Fax: (508) 977-6979

Date of Submission: November 4, 2016

II. Device

Device Proprietary Name	Codman Integrated Bipolar Cord and Tubing Set
Common Name	Irrigation Tubing and Bipolar Cord
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 Codman Integrated Irrigation Tubing and Bipolar Cord Set (K052449), which was cleared on October 17, 2005.

IV. Device Description

The CODMAN Integrated Bipolar Cord and Tubing Set consists of an inlet spike with protective cap, an on/off clamp, silicone tubing and fittings, a male luer connector, two plugs, and a female socket connector. The set is packaged sterile for single use with a nonpyrogenic fluid pathway.

V. Indications for Use

The CODMAN Integrated Bipolar Cord and Tubing Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation.

VI. Comparison to Predicate Device

The Codman Bipolar Cord and Tubing Set is substantially equivalent to the predicate device, and eligible for the Special 510(k) process, as the proposed device has the following similarities to the predicate 510(k) device:

- the same indications for use,
- the same intended use,
- use the same fundamental scientific technology,
- incorporates the same basic cord and tube set design,
- incorporates similar materials,
- packaged and sterilized using the same packaging design, materials, and processes.

The minor differences between the predicate and subject device are:

- a slight difference in device design,
- minor formulation changes to the existing materials (material types are remaining the same), and
- change in shelf life.

The table below details the comparison of the predicate and subject devices.

Comparison of the Predicate and Subject Device		
	Predicate Device: Codman Integrated Irrigation Tubing and Bipolar Cord Set (K052449)	**Subject Device: Codman Integrated Bipolar Cord and Tubing Set (This Submission)**
FDA Regulatory Information		
Manufacturer	Codman & Shurtleff, Inc.	Same as predicate
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		
Indications for Use	The CODMAN Integrated Bipolar Cord and Tubing Sets are intended to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation. [They are intended for use with the Codman/Malis CMC-II and the Codman/Malis CMC III I.E.C. Irrigation Modules and the Codman/Malis Bipolar Coagulators.]	Same as predicate
Device Design		
Single Use	Yes	Same as predicate
Device Design	Integrated disposable bipolar cord with an irrigation tube.	Same as predicate
	Comprised of irrigation inlet spike with protective cap, male luer connector, female	Same as predicate

Comparison of the Predicate and Subject Device		
	Predicate Device: Codman Integrated Irrigation Tubing and Bipolar Cord Set (K052449)	**Subject Device: Codman Integrated Bipolar Cord and Tubing Set (This Submission)**
	socket connector, on/off clamp, silicone tubing and fittings, and two bipolar generator plug components.	
Devices for which this Accessory is to be used with	They are intended for use with the Codman/Malis CMC-II and the Codman/Malis CMC III I.E.C. Irrigation Modules and the Codman/Malis Bipolar Coagulators.	Same as predicate
Device Color	**Bipolar Cord** Transparent tubing surrounding copper cord with white plugs and socket **Irrigation Tubing** Transparent tubing and connectors with white inlet spike	Same as predicate
Device Materials		
Spike	ABS	ABS
PVC Tubing	PVC	PVC
Tubing Adaptor	PVC	Gravity Feed: PVC Rotary Pump: ABS
Silicone Tubing	Silicone	Silicone
Extruded PVC/ Copper Cable	PVC and Copper	PVC and Copper
Male Slip Luer	PVC	PVC
Bushing	PVC	PVC
Spike Cap	Polyethylene	Polyethylene
Tubing Clamp	Polyethylene, Polysterene, Polypropylene	Celanese and Polyacetal
Male Slip Luer Cap	Polyethylene	Polyethylene
Banana Plug Pin	nickel plate brass	nickel plate brass
Banana Plug Overmold	PVC	PVC
Socket	nickel plated brass	tin plated brass
Socket Overmold	PVC	PVC
Other		
Electrical Safety Testing	Testing in accordance with: • ANSI/AAMI HF18:2001	Testing in accordance with • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-2
Packaging Configuration (Sterile Barrier)	Peel Pouch	Same as predicate

Comparison of the Predicate and Subject Device		
	Predicate Device: Codman Integrated Irrigation Tubing and Bipolar Cord Set (K052449)	**Subject Device: Codman Integrated Bipolar Cord and Tubing Set (This Submission)**
Packaging Materials (Sterile Barrier)	Transparent bottom stock formable film-thermoform and 1073B Tyvek top stock thermoform	Same as predicate
Packaging Unit	10 units per box	Same as predicate
Sterility Assurance Level (SAL)	10^{-6}	Same as predicate
Sterilization Method	Ethylene oxide	Same as predicate
Shelf Life	5 years	1 year

VII. Performance Data

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

Please see the Summary of Testing table below for a summary of testing and testing results. Additional information regarding the Bench, Electrical Safety, Sterilization, Shelf Life and Biocompatibility Testing follows.

Summary of Testing	
Test	**Result**
Bench Testing	
Electrical Functionality Test – Continuity and Resistance	Pass
Irrigation Functionality Test – Leak (Dry)	Pass
Mating Part – Part 1: Pins	Pass
Mating Part – Part 2: Socket	Pass
Mating Part – Part 3: Luer	Pass
Mating Part – Part 4: Spike	Pass
Pull Testing	Pass
Irrigation Simulated Use Test	Pass
Simulated Use Pull Test	Pass
Electrical Safety and EMC per IEC 60601	
High Frequency Leakage Current – 60601-1 and 60601-2-2	Pass
High Frequency Dielectric Strength – 60601-1 and 60601-2-2	Pass
Main Frequency Dielectric Strength – 60601-1 and 60601-2-2	Pass
Cable Flexing – 60601-1 and 60601-2-2	Pass
Electromagnetic Compatibility – 60601-1-2	Pass
Sterilization	
Bioburden Validation	Pass
Bioburden Test	Pass
EO/ECH Residuals	Pass
LAL Validation	Pass

Shelf Life – Functionality Testing Complete after One Year Accelerated Aging	
Electrical Functionality Test – Continuity and Resistance	Pass
Irrigation Functionality Test – Leak (Dry)	Pass
Mating Part – Part 1: Pins	Pass
Mating Part – Part 2: Socket	Pass
Mating Part – Part 3: Luer	Pass
Mating Part – Part 4: Spike	Pass
Pull Testing	Pass
Biocompatibility	
Cytotoxicity – ISO MEM Elution	Pass
Delayed Type Sensitization – ISO Maximization in Guinea Pigs	Pass
Intracutaneous Reactivity – ISO Intracutaneous Study in Rabbits	Pass
Acute Systemic Toxicity – ISO Systemic Toxicity in Mice	Pass
Pyrogenicity Testing – USP Rabbit Pyrogen Study, Material Mediated	Pass
Hemolysis – ASTM F756 (Extract only)	Pass
Chemical Characterization of Extractables (ISO 10993-18)	Low level of extractables
Toxicology Risk Assessment	Extractables do not represent a significant toxicological risk to patients

Bench Testing

Bench testing data demonstrated that the Codman Integrated Bipolar Cord and Tubing Set performed according to its description and intended use, and established the performance characteristics of this device. The Codman Integrated Bipolar Cord and Tubing Set passed each bench test conducted, as compared to the device characteristics and performance specifications of the predicate device. Clinical testing was not required to establish substantial equivalence.

Results of verification and validation testing conducted on Codman Integrated Bipolar Cord and Tubing Set demonstrated that the proposed device performed as designed, is suitable for the intended use, and is substantially equivalent to the predicate device.

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.

Electrical Safety and Electromagnetic Compatibility Testing

Electrical safety testing was conducted in accordance with IEC 60601-1 *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*. Electromagnetic Compatibility Testing

(EMC) was 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 disturbances - Requirements and tests.* The Codman Integrated Bipolar Cord and Tubing Set passed all electrical safety and EMC testing.

Sterilization

The Codman Integrated Bipolar Cord and Tubing Sets are sterilized via ethylene oxide. The Cord and Tubing Sets have been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135:2014 Sterilization of health care products – Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices and ISO 11737-1:2006, "Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products." Sterilization testing also demonstrated that ethylene oxide residuals can be reduced to an acceptable level in accordance with ISO 10993-7:2008 Biological Evaluation of Medical Devices – Ethylene Oxide Sterilization Residuals and the proposed device can be successfully adopted into Codman's existing sterilization cycle.

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. The Codman Integrated Bipolar Cord and Tubing Set was subjected to accelerated aging. The aging studies established that the device and packaging remain functional and maintain sterility for 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.

Animal Studies

No animal studies were performed as appropriate verification and validation of the modified device was achieved 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 modified device was achieved from the results of the bench testing,

biocompatibility evaluation, and electrical/safety testing.

VIII. Conclusion

Based upon the same indications for use, intended use, fundamental scientific technology, material types, comparison to the predicate device, and testing conducted, it is concluded that the subject device, the Codman Bipolar Cord and Tubing Set, is substantially equivalent to the predicate device, the Codman Integrated Irrigation Tubing and Bipolar Cord Set (K052449), and therefore does not raise any new issues of safety and effectiveness.