July 31, 2020

BiPad Surgical, Inc.
% Rafael Aguila
Responsible Third-Part Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 403
Ludlum, Florida 33155

Re: K201833
Trade/Device Name: BiPad Hand Activated, Disposable Bipolar Electrocautery Cords Model BP105-C (Codman) and Model BP105-M (Medtronic)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 1, 2020
Received: July 2, 2020

Dear Rafael Aguila:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Section 4 – Indications for Use Statement (FDA 3881)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201833

Device Name

BIPAD Hand Activated, Disposable Bipolar Electrocautery Cords, Model BP105-C (Codman) and Model BP105-M (Medtronic)

Indications for Use *(Describe)*

BIPAD Hand Activated, Disposable Bipolar Electrocautery Cords are intended to connect an electrosurgical device to and electrosurgical generator. They are indicated for use with bipolar forceps during general surgical procedures.

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

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the BIPAD® Hand Activated, Disposable Electrocautery Cords, Model BP105-C (Codman) and Model BP105-M (Medtronic).

Submitted by:	BiPAD Surgical, Inc. 110 Ocean Blvd. Point Lookout, NY 11569
Date:	April 30, 2020
Contact Person:	Louis Cornacchia, MD Chief Executive Officer lcornacchia@bipadsurgical.com
Proprietary Name:	BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords, Model BP105-C (Codman) and BP105-M (Medtronic)
Common Name:	Disposable Bipolar Electrocautery Cord
Classification Name and Reference:	21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories, Device Class II
Device Product Code, Device Panel:	GEI, General & Plastic Surgery
Predicate Device:	Kepler MedTec Disposable Bipolar Cable (K110462)

5.1 Device Description

The BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords, Model BP105-C (Codman) and BP105-M (Medtronic) have been designed as an accessory to electrosurgical instruments where bipolar electrosurgical coagulation is desired during surgery. The device is a sterile, disposable, bipolar cord that connects to the electrosurgical generator on one end and the active instrument (bipolar forceps) on the other end. The cord has an integrated hand switch to activate the coagulating current of the RF generator. The device is intended for use with currently marketed Electrosurgical generators and bipolar surgical forceps to control bleeding.

The BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords are compatible with FDA cleared and marketed Codman and Medtronic Electrosurgical Generators and FDA cleared bipolar forceps using standard US connection spaced pins. We have provided minimum specifications for use with the subject device with other electrosurgical generators using Medtronic style connectors with a fixed pin spacing and/or Codman generators with the identified bipolar connection pin spacing.

Device Components

BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords consist of:

1) A connector specific to the intended electrosurgical generator (Codman type or Medtronic type)
2) A cable capable of carrying the high frequency coagulation current from the electrosurgical generator to the surgical forceps
3) BiPad Actuator Assembly which consists of the integrated hand switch, an actuator arm, and a molded housing.

The actuator assembly is designed to be removable from the housing to allow the surgeon to use the cord as a traditional disposable electrocautery cord (no hand switch) if desired. When used in this configuration, a foot switch (foot pedal) is required to control the generator output.

The BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords will be available in two configurations that are essentially identical except for the proximal connection to the intended electrosurgical generator. The Model BP105-M (Medtronic) is compatible with any electrosurgical generator that accepts the standard 3-prong, molded bipolar plug with fixed pin spacing such as Medtronic generators.

The BP105-C (Codman) is compatible with the Codman Malis generators. Both models of the subject device have the same cord, cord length and integrated hand switch.

The Codman version, Model BP105-C, requires an additional Y-connector accessory (BP105-CY). The Y-connector (BP105-CY) allows the hand switch on the Codman version of the cord to share control of the flow of energy from the generator to the forceps with the existing foot pedal. It is intended that the Y-connector will be attached to the Codman Malis generator using the supplied adhesive and remain with the generator. This accessory is provided non-sterile and is intended to be reusable.

The BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords are meant to be used in a surgical setting. These are single use devices that should not be reprocessed or reused. The cords will be EO sterilized and have a shelf life of 12 months.

5.2 Intended Use / Indication for Use

The BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords are intended to connect an electrosurgical device to an electrosurgical generator. They are indicated for use with bipolar forceps during general surgical procedures.

5.3 Contraindications

The BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords should not be used for laparoscopic procedures.

5.4 Technology and Fundamental Scientific Technology

BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords work together with FDA cleared and marketed bipolar electrosurgical generators and FDA cleared and marketed 2-prong standard bipolar surgical forceps.

BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords have an integrated hand switch in the cord near the forceps socket, which allows activation of the electrocautery current from the attached generator.

The Model BP105-M (Medtronic) cord has a molded three prong connector which allows the hand switch to share the foot pedal circuit to activate the generator.

The Model BP105-C (Codman) cord connects the hand switch in parallel with the foot pedal switch using the BP105-CY Y-connector accessory as a splitter. This allows both the hand switch and the foot pedal switch to close the pedal circuit to activate the generator's electrocautery current.

5.5 Determination of Substantial Equivalence

BiPad Surgical, Inc. claims that the BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords are substantially equivalent to the predicate device, (Kepler MedTec Disposable Bipolar Cable, K110462). BiPAD Surgical claims this equivalence because the proposed device has an equivalent intended use, manufacturing materials, operating principles and specifications, target population, clinical setting and environment requirements, sterilization method, physical and operational specifications, and electrical safety characteristics. The comparison of these specifications demonstrates the functional equivalence of the products

BiPAD Surgical believes that the differences that exist in working mechanism and structure between the BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords and the predicate (i.e. finger switch and cable length) are addressed in the Intertek Electrical Safety reports and have been addressed in the Risk Management File for the device. The differences do not raise new issues of safety and effectiveness. Verification and Usability testing demonstrated that no adverse effects have been introduced by these differences.

BiPad Surgical, Inc. believes that the BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords are as safe and effective and perform in a substantially equivalent manner to the predicate device.

5.6 Summary of Non-Clinical Tests

The BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords, Model BP105-C (Codman) and BP105-M (Medtronic) have been evaluated for biocompatibility, sterilization, distribution, usability, as well as electrical, electromagnetic, and mechanical safety and has been found to conform with applicable medical device safety standards. The BiPAD® Hand Activated, Disposable Bipolar Electrocautery Cords comply with voluntary standards and FDA Guidance documents. The following performance data has been provided in support of the substantial equivalence determination. All testing was performed on final devices.

5.6.1 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.

5.6.2 Electrical Safety and EMC

Electrical safety and EMC testing were conducted in accordance with:

- AAMI/ANSI ES 60601-1 (2012), Medical Electrical Equipment –Medical electrical equipment-Part1: General requirements for basic safety and essential performance
- 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
- IEC 60601-1-6 (2013), Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-2 (2017), 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.

5.6.3 Biocompatibility

The subject device passed all required biocompatibility tests per:

- ISO 10993-1 (2018) Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process
- ISO10993-5 (2009), Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO10993-10 (2010), Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- Guidance for Industry and FDA Staff – *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)*

5.6.4 Sterilization

The BIPAD® Hand Activated, Disposable Bipolar Electrocautery Cord is provided sterile using a validated ethylene oxide (EO) sterilization cycle. The sterilization cycle has 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 11138-1 Sterilization of health care products, Biological indicators – Part 1: General requirements.

5.6.5 Packaging & Distribution

Packaging Performance testing was successfully completed per the standards listed below prior to, and immediately following, accelerated age conditioning to support the proposed shelf life. Real time aging is in process.

- ISO 11607-1:2019 Packaging for Terminally Sterilized Medical Devices, Part 1
- ISO 11607-2:2019 Packaging for Terminally Sterilized Medical Devices, Part 2
- ASTM D4169-16 (2016) Standard Practice for Performance Testing of Shipping Containers

5.6.6 Other

- ISO 15223-1 (2016), Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
- ISO14971 (2007), Medical device - Application of risk management to medical devices
- Guidance for Industry and Staff, *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery* (issued March 24, 2014)
- Guidance for Industry and Staff, *Applying Human Factors and Usability Engineering to Medical Devices* (issued February 3, 2016)
- FDA Guidance, *Design Control Guidance for Medical Device Manufacturers* (issued March 11, 1997)
- FDA Guidance for Industry, *Pyrogen and Endotoxins Testing: Questions and Answers* (issued June 2012)
- Guidance for Industry and Staff, *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (issued January 21, 2016)
- Guidance for Industry and Staff, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (issued March 17, 2015)

5.7 Summary of Clinical Tests

The proposed BIPAD® Hand Activated, Disposable Bipolar Electrocautery Cord did not require formal clinical study since substantial equivalence to the legally marketed predicate device was proven with verification/validation testing.

5.8 Conclusion

It was determined through comparison with the predicate device (Kepler MedTec Disposable Bipolar Cable - K110462) and device testing that the BIPAD® Hand Activated, Disposable Bipolar Electrocautery Cord is safe and effective and does not raise any new questions of safety and effectiveness and is therefore considered substantially equivalent.