March 20, 2020

Encision Incorporated
% Charles Hart
Principle Consultant
HART Consulting LLC
615 Reid Place
Castle Rock, Colorado 80108

Re: K191612
Trade/Device Name: Encision AEM Monopolar Laparoscopic Instruments and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting & Coagulation Devices and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 18, 2020
Received: February 21, 2020

Dear Charles Hart:

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

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)*
K191612

Device Name
Encision AEM® (Active Electrode Monitoring) Monopolar Laparoscopic Instruments and Accessories

Indications for Use *(Describe)*
These AEM Instruments incorporate the use of AEM technology and are intended for use in delivering monopolar electrosurgical energy during laparoscopic procedures only. AEM Instruments are intended for use with the AEM Monitoring System and electrosurgical generators having compatibility with the AEM Monitor. Scissors Inserts are intended for use on soft tissue only.

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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K191612 510(k) Summary

Device: Encision AEM® (Active Electrode Monitoring) Monopolar Laparoscopic Instruments and Accessories

Owner: Encision Inc.

Contact: Greg Trudel
President & CEO
6797 Winchester Circle
Boulder, CO, 80301, USA
gtrudel@encision.com
303-444-2600

Date: 20 Mar 2020

Subject Device:

Trade Name	See table below
Common Name	Monopolar laparoscopic accessory
Regulation Name	Electrosurgical, Cutting & Coagulation, Accessories
Regulation Number	21 CFR 878.4400
Product Code	GEI
Device Class	2
Review Panel	General and Plastic Surgery
Prior Submissions	No prior submissions for the subject device

Primary Predicate Devices:

Trade Name	See table below
Regulation Name	Electrosurgical, Cutting & Coagulation, Accessories
Manufacturer	Encision Inc.
510(k) Number	K912780

Secondary Predicate Devices:

Trade Name	ES03XX Series
Regulation Name	Electrosurgical, Cutting & Coagulation, Accessories
Manufacturer	Encision Inc.
510(k) Number	K091074

Device Description:

Encision AEM® Monopolar Laparoscopic Instruments and Accessories incorporate the use of AEM technology and are intended for use in delivering monopolar electrosurgical energy during laparoscopic procedures only. Encision AEM® Monopolar Laparoscopic Instruments and Accessories are intended for use with the AEM Monitoring System and electrosurgical generators having compatibility with the AEM Monitor. These Encision AEM® Monopolar Laparoscopic Instruments and Accessories include reusable handles and reusable & disposable insert electrodes plus disposable sheath. Encision AEM® Monopolar Laparoscopic Instruments and Accessories, in conjunction with an AEM Monitor properly connected to the electrosurgical generator (ESU), continuously monitor and dynamically manage "stray energy" (insulation failure and capacitive coupling), which are likely out of the surgeon's field of view.

Model Numbers and Trade Names:

Model Number (subject device)	**Trade Name**	**Product Family**	**Predicate Device (K912780)**
ES0101	AEM e·Edge® Curved Scissors, 1/2″Insert	Disposable Scissors	ES0101
ES0102	AEM e·Edge® Curved Scissors, 3/4″ Insert	Disposable Scissors	ES0102
ES0110	AEM e·Edge® Hook Scissors Insert	Disposable Scissors	ES0110
ES0120	AEM e·Edge® Scissors, 3/4″, Low Profile Insert	Disposable Scissors	ES0120
ES8000 Series	AEM enTouch® Handles	AEM® Handles (Reusable)	ES5700
ES8200 Series	AEM enTouch® Handles with Indexing and Locking	AEM® Handles (Reusable)	ES5700
ES0004	AEM® Right Angle Dissector Insert	Reusable Inserts	ES0004
ES0008	AEM® Tapered Right Angle Dissector Insert	Reusable Inserts	ES0008
ES0009	AEM® Blunt Nose Grasper Insert	Reusable Inserts	ES0009
ES0011	AEM® Short Right Angle Dissector Insert	Reusable Inserts	ES0011
ES0012	AEM® Bottle Nose Grasper Insert	Reusable Inserts	ES0012
ES0013	AEM® Bullet Nose Grasper Insert	Reusable Inserts	ES0013
ES0014	AEM® Fine Tooth Fenestrated Grasper Insert	Reusable Inserts	ES0014
ES0501	AEM® Curved Maryland Dissector Insert	Reusable Inserts	ES0501
ES0506	AEM® 90° Grasper Insert	Reusable Inserts	ES0506
ES0507	AEM® Fenestrated Grasping Forceps Insert	Reusable Inserts	ES0507
ES0508	AEM® Round Nose Grasper Insert	Reusable Inserts	ES0508

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Model Number (subject device)	Trade Name	Product Family	Predicate Device (K912780)
ES0509	AEM® Pointed Nose Grasper Insert	Reusable Inserts	ES0509
ES0510	AEM® Petelin Dissector Insert	Reusable Inserts	ES0510
ES0511	AEM® Dolphin Nose Grasper Insert	Reusable Inserts	ES0511
ES0512	AEM® Long Dolphin Nose Grasper Insert	Reusable Inserts	ES0512
ES0513	AEM® Straight Dissector Insert	Reusable Inserts	ES0513
ES0514	AEM® Standard Grasper Insert	Reusable Inserts	ES0514
ES0521	AEM® Bowel Grasper Insert	Reusable Inserts	ES0521
ES0522	AEM® Fenestrated Bowel Grasper Insert	Reusable Inserts	ES0522
ES0526	AEM® Tapered Maryland Dissector Insert	Reusable Inserts	ES0526
ES0533	AEM® Strong Curved Maryland, 7-8mm Insert	Reusable Inserts	ES0533
ES0535	AEM® Endo Cinch Extreme Atraumatic Serrated Insert	Reusable Inserts	ES0535
ES0537	AEM® Wave Grasper Insert	Reusable Inserts	ES0537
ES0538	AEM® Mixter Clamp, 90° Long Insert	Reusable Inserts	ES0538
ES0541	AEM® Kelly Forceps Insert	Reusable Inserts	ES0541
ES0543	AEM® Maxi Grasper Insert	Reusable Inserts	ES0543
ES0547	AEM® Maryland Dissector, Diamond Serrations Insert	Reusable Inserts	ES0547
ES0548	AEM® Dissecting Forceps, Right Angled Insert	Reusable Inserts	ES0548
ES0549	AEM® Maryland Dissector, Aggressive Insert	Reusable Inserts	ES0549
ES0552	AEM® Dissecting Forceps, Right Angled, Cross Serrated Insert	Reusable Inserts	ES0552
ES0553	AEM® Straight Micro-Grasper Insert	Reusable Inserts	ES0553
ES0557	AEM® Micro-Fenestrated Grasper Insert	Reusable Inserts	ES0557
ES0558	AEM® Tapered Micro-Fenestrated Grasper Insert	Reusable Inserts	ES0558
ES0559	AEM® Right Angle Dissector, 7mm, Diagonal Serrations Insert	Reusable Inserts	ES0559
ES0565	AEM® Maryland Dissector with 90° Tooth Insert	Reusable Inserts	ES0565
ES0566	AEM® Beveled Maryland Dissector, Tapered Insert	Reusable Inserts	ES0566
ES0570	AEM® Insert, Atraumatic Grasper (Single Action)	Reusable Inserts	ES0570

Model Number (subject device)	Trade Name	Product Family	Predicate Device (K912780)
ES0571	AEM® Insert, Traumatic Grasper	Reusable Inserts	ES0571
ES0573	AEM® Insert, Traumatic Grasper (Single Action)	Reusable Inserts	ES0573
ES0574	AEM® Insert, Fenestrated Bowel Grasper	Reusable Inserts	ES0574
ES0001	AEM® Curved Scissors, 1/2″ Insert	Reusable Inserts	ES0001
ES0002	AEM® Curved Scissors, 3/4″ Insert	Reusable Inserts	ES0002
ES0010	AEM® Hook Scissors Insert	Reusable Inserts	ES0010
ES0150 Series	AEM® Disposable Sheath	Disposable Sheaths	ES0150

Indications for Use:

These AEM Instruments incorporate the use of AEM technology and are intended for use in delivering monopolar electrosurgical energy during laparoscopic procedures only.

AEM Instruments are intended for use with the AEM Monitoring System and electrosurgical generators having compatibility with the AEM Monitor.

Scissors Inserts are intended for use on soft tissue only.

Sterility/Packaging:

The Disposable Scissors and Disposable Sheaths are supplied sterile per ANSI/AAMI/ISO 11137-1:2006 and ANSI/AAMI/ISO 11607-1:2006. The products are sterilized using E-beam radiation sterilization to achieve 10^{-6} SAL. Product is packaged in a Tyvek mylar pouch (10 pouches in a box) with a 5 year shelf life in the sterile packaging.

The AEM® Handles and Reusable Inserts are reusable and are cleaned and steam sterilized for repeated use per ANSI/AAMI/ISO 17664:2017 and ANSI/AAMI/ISO 17665-1:2006. These instruments are cleaned using manual, automatic or combined manual/automatic cleaning methods. They are sterilized through Prevac steam sterilization using FDA-cleared sterile wraps to achieve 10^{-6} SAL. These products are shipped non-sterile and require sterilization before use.

Biocompatibility:

All patient contact materials are biocompatible. Material testing demonstrates conformance with ANSI/AAMI/ISO 10993-1:2009, 4th edition. Gap analysis 05927 demonstrates that testing to a previous revision of the standard is consistent with the current recognized revision of ISO 10993-1.

Standards:

The AEM® Monopolar Laparoscopic Instruments and Accessories have been tested to show conformity to the following FDA recognized standards:

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Topic	Standard Used	Application
E-beam sterilization	ANSI/AAMI/ISO 11137-1:2006 Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices	Disposable Scissors and Disposable Sheaths are sterilized to 10^{-6} SAL using E-beam sterilization in accordance with this standard.
Sterile packaging	ANSI/AAMI/ISO 11607-1:2006 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems	Disposable Scissors and Disposable Sheaths are packaged with a sterile barrier system in accordance with this standard.
Reprocessing – cleaning and sterilization	ANSI/AAMI/ISO 17664:2017 Processing of Health Care Products – Information to be Provided by the Medical Device Manufacturer for the Processing of Medical Devices	AEM® Handles and Reusable Inserts are reprocessed for reuse in accordance with this standard
Reprocessing – steam sterilization	ANSI/AAMI/ISO 17665-1:2006 Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routing Control of a Sterilization Process for Medical Devices	AEM® Handles and Reusable Inserts are reprocessed to 10^{-6} SAL using steam sterilization in accordance with this standard.
Biocompatibility	ANSI/AAMI/ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process	All patient-contact materials for the AEM® Monopolar Laparoscopic Instruments and Accessories have been tested for biocompatibility in accordance with this standard.
Electromagnetic compatibility	ANSI/AAMI/IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance. Collateral Standard. Electromagnetic Compatibility. Requirements and Tests	The AEM® Monitoring System in which these electrodes are an accessory has been tested for electromagnetic compatibility in accordance with this standard.
Electrical safety	ANSI/AAMI/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	The AEM® Monitoring System in which these electrodes are an accessory has been tested for electrical safety in accordance with this standard.
Labeling	ANSI/AAMI/ISO 15223-1:2016 Medical Devices – Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied – Part 1: General Requirements	The AEM® Monopolar Laparoscopic Instruments and Accessories have associated labeling in accordance with this standard.

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Topic	Standard Used	Application
Risk management	ANSI/AAMI/ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices	Risk management activities for the AEM® Monopolar Laparoscopic Instruments and Accessories have been conducted in accordance with this standard.

Technological Characteristics:

The technological characteristics of the subject device are identical to the predicate devices with regards to fundamental design, materials, operating principle, use, compatibility, packaging and sterilization. The accessories have both 35cm and 45cm configurations. The changes over time to the predicate devices do not introduce new concerns of safety or effectiveness. The differences between the subject and predicate device are:

- Use of Metrilube Instrument Lubricant for Disposable and Reusable Scissors for effective cutting performance. The lubricant is a patient-contact material and is biocompatible.
- Change from a removable trigger to a permanent trigger on the AEM® Handles for improved handle performance. The fundamental technology and operating principle is identical to the predicate devices.
- Shelf life of Disposable Scissors and Disposable Sheaths has increased from 1 year to 5 years in the sterile packaging.

Substantial Equivalence:

The subject device is substantially equivalent to the predicate device, as there is no change to the Intended Use, Operating Principle, Patient Contact Materials, Fundamental Technology, Sterilization and Performance.

Topic	Subject Device (this submission) compared to Predicate Devices (K912780)
Indications for Use	No change to Intended Use.
Operating Principle	No change to Operating Principle.
Materials	Substantially equivalent. Material changes are equivalent to predicate devices and do not add new biocompatibility concerns.
Use	No changes to Use. The AEM Instruments are prescription use only.
Technology	Only minor changes to Technology. The design changes made to the products have not affected the fundamental technology of the AEM Instruments.
Sterilization	No changes to Sterilization. Disposable Scissors and Disposable Sheaths are E-beam sterilized and supplied sterile. AEM Handles and Reusable Inserts are reusable and supplied non-sterile.
Storage & Transportation	No change to Storage and Transportation.
Performance	No change to Performance.

Bench Testing:

All testing required per design control procedures was conducted using bench testing. Performance analysis has shown the Encision AEM® Monopolar Laparoscopic reusable handpieces and Encision AEM® Monopolar Laparoscopic reusable & disposable insert electrodes plus disposable sheath to perform as intended and as well as the predicate devices under the same and/or similar conditions. These devices have been tested with settings set equal to those seen in typical procedures where these devices would be indicated for use. The requirements for electrodes function in the AEM Monitoring System have not changed from the original 510(k) submissions. The tests conducted show that the changes since the original 510(k) submissions demonstrate conformity to the original internal and regulatory requirements. No differences have been observed between the performance of the predicate devices and the device subject of this 510(k) Notification submission. No animal or clinical testing is required.

Conclusion:

The AEM® Monopolar Laparoscopic Instruments and Accessories are substantially equivalent to the predicate devices. The design changes do not introduce new safety or effectiveness concerns and do not alter the fundamental technology or operating principle of the devices. The Intended Use is identical. Bench testing data has confirmed substantial equivalence to the predicate devices.