July 15, 2020

Encision Inc.
Pete Geary
VP Operations
6797 Winchester Circle
Boulder, Colorado 80260

Re: K201018
Trade/Device Name: Encision AEM enTouch 2X Scissor
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 17, 2020
Received: June 19, 2020

Dear Pete Geary:

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)*
K201018

Device Name
Encision AEM (Active Electrode Monitoring) enTouch® 2X Scissor

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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K201018 510(k) Summary

Device: Encision AEM (Active Electrode Monitoring) enTouch® 2X Scissor

Owner: Encision Inc.

Contact: Pete Geary
VP Operations
6797 Winchester Circle
Boulder, CO, 80301, USA
303-444-2600
pgeary@encision.com

Submission Date: 14 July 2020

Subject Device:

Trade Name	AEM enTouch® 2X Scissors
Model Number	ES0201, ES0201-45, ES0202, ES0202-45
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

Primary Predicate Device:

Trade Name	ES000X, Reusable Scissor
Regulation Name	Electrosurgical, Cutting & Coagulation, Accessories
Manufacturer	Encision Inc.
510(k) Number	K191612

Reference Predicate Device:

Trade Name	ES01XX, Disposable Scissor
Regulation Name	Electrosurgical, Cutting & Coagulation, Accessories
Manufacturer	Encision Inc.
510(k) Number	K191612

Special 510(k) Decision:

The 2X Scissor is a modified version of the AEM Reusable Scissor, which was FDA cleared on K191612.

The change adds a thermochromic indicator to the scissor that allows the user to reprocess the device for one more use, supplies the device sterile and changes the stainless-steel materials. This is a change from the Reusable Scissor, which is supplied non-sterile. The 2X Scissor is supplied sterile with a black indicator. It can be reprocessed for one further use via the same validated method as the AEM Reusable Scissor. The indicator changes color from black to orange following steam sterilization. The indicator is non-patient contact. The materials are changed from 420 SS and 17-4 PH SS to 303 SS and 17-4 PH SS. No changes have been made to the fundamental design. The changes to the device can be evaluated using well-established methods.

The changes are summarized below:

Change	**2X Scissor (subject device)**	**Reusable Scissor (K191612 primary predicate device)**	**Comments**
Scissor Rod	-Thermochromic indicator on shaft	-No indicator on shaft	None
Material	-303 and 17-4 PH stainless-steel	-420 and 17-4 PH stainless-steel	Material is identical to reference predicate Disposable Scissor (K191612).
Sterilization	-Supplied sterile (E-beam	-Supplied non-sterile	Sterilization method is identical to reference predicate Disposable Scissor (K191612).
Packaging	-Sterile barrier system, 10 per box	-Poly bag, 1 per bag	Packaging configuration is identical to reference predicate Disposable Scissor (K191612).
Cleaning	-Reprocessed for 2 uses	-Reprocessed for up to 20 uses	No change to cleaning and steam sterilization method.
Labeling	-Temperature limit symbol -Humidity limit symbol -Sterile symbol -Do not use damaged package symbol	-No temperature limit symbol -No humidity limit symbol -Non-sterile symbol -No do not use damaged package symbol	None

Device Description:

2X Scissor Insert – ES02XX Series

The AEM enTouch® 2X Scissors Inserts are designed for use with the ES8000 / ES8200 series AEM enTouch® Handles. All scissors will fit through standard 5.5mm trocars.

Model Numbers and Trade Names:

Predicate Device Model Number and Trade Name (original device, K191612)	**Subject Device Model Number and Trade Name (modified device, K201018)**
ES0001, AEM® Curved Scissors, 1/2" Insert, 35cm	ES0201, AEM enTouch® 2X Scissor, ½", 35cm
ES0001-45, AEM® Curved Scissors, 1/2" Insert, 45cm	ES0201-45, AEM enTouch® 2X Scissor, ½", 45cm
ES0002, AEM® Curved Scissors, 3/4" Insert, 35cm	ES0202, AEM enTouch® 2X Scissor, ¾", 35cm
ES0002-45, AEM® Curved Scissors, 3/4" Insert, 45cm	ES0202-45, AEM enTouch® 2X Scissor, ¾", 45cm

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:

This product is supplied sterile per ANSI/AAMI/ISO 11137-1:2006 and ANSI/AAMI/ISO 11607-1:2006. The product is sterilized using E-beam sterilization to achieve 10^{-6} SAL. Product is packaged in a Tyvek mylar pouch (10 pouches in a box) with a 1.5 year shelf life in the sterile packaging.

The product may be cleaned and steam sterilized for one more use per ANSI/AAMI/ISO 17664:2017 and ANSI/AAMI/ISO 17665-1:2006. The product is cleaned using manual, automatic or combined manual/automatic cleaning methods. Product is sterilized through Prevac steam sterilization using FDA-cleared sterile wraps to achieve 10^{-6} SAL. After steam sterilization product may be used one additional time before end of life conditions are met.

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. The product is not made with natural rubber latex.

Standards:

The AEM enTouch® 2X Scissors have been tested to show conformity to the following FDA recognized standards:

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	The 2X Scissors 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	The 2X Scissors 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	The 2X Scissors are reprocessed for one more use 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	The 2X Scissors 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 2X Scissors 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 scissors 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 scissors are an accessory has been tested for electrical safety in accordance with this standard.

Topic	Standard Used	Application
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 2X Scissors have associated labeling in accordance with this standard.
Usability	ANSI/AAMI/IEC 63266-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices	The 2X Scissors have been designed for safe usability in accordance with this standard.
Risk management	ANSI/AAMI/ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices	Risk management activities for the 2X Scissors have been conducted in accordance with this standard.

Technological Characteristics:

The technological characteristics of the subject device are identical to the Reusable Scissor with regards to fundamental design, operating principle, use, compatibility and reprocessing method. The differences between the subject and predicate device are:

- The addition of a thermochromic indicator on the shaft of the insert, which changes color from black to orange as a result of steam sterilization following the first use of the device. The rod diameter is reduced where the indicator is applied. The indicator is a non-patient contact material and biocompatible.
- The scissor is made with 303 and 17-4 PH stainless-steel materials.
- The scissor is provided sterile to 10^{-6} SAL.
- The scissor may be reprocessed and reused only once.

Equivalence:

The subject device is substantially equivalent to the predicate device, as there is no change to the Indications for Use, Operating Principle, Patient Contact Materials, Fundamental Technology, Performance and EMC. The differences between the subject and predicate device are the addition of a thermochromic indicator on the insert shaft, supplying the device sterile and the stainless-steel material. The indicator is for reference only and does not raise new concerns of safety or effectiveness.

Topic	Subject Device (this submission) compared to Predicate Device (K191612)
Intended Use	No change to Intended Use.
Operating Principle	No change to Operating Principle.
Materials	Substantially equivalent. Addition of indicator made from thermochromic epoxy, which is non-patient contact. Changes to stainless steel grade does not affect fundamental design or reprocessing.
Use	Substantially equivalent. The scissor may be reprocessed and used a second time. No other changes to use.

Topic	Subject Device (this submission) compared to Predicate Device (K191612)
Technology	Substantially equivalent. Addition of thermochromic indicator that changes color to show the insert can be used one more time. No change to fundamental technology.
Sterilization	Substantially equivalent. The scissor is provided sterile to 10^{-6} SAL following E-beam sterilization. It can be cleaned and steam sterilized for one more use via the same validated method as the Reusable Scissor.
Performance	No change to Performance.
Storage & Transportation	Substantially equivalent. The scissor has storage temperature and humidity limits so that the indicator does not change color in the sterile packaging. No change to safety or effectiveness.
EMC	No change to EMC or Electrical Safety. The AEM System in which the scissor is an accessory has been tested.

Bench Testing:

All testing required per design control procedures was conducted using bench testing. Performance analysis has shown the Encision AEM enTouch® 2X Scissors to perform as intended and as well as the predicate device under the same and/or similar conditions. The subject device has 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.

Risk Analysis:

Risk Assessment Summary:

Change (from predicate)	Risks	Risk Category (see chart below)	Verification Method / Standard Used	Acceptance Criteria	Results (Pass/Fail)
Addition of indicator	Impossible or difficult assembly into handle due to indicator diameter being too large	C	Direct Measurement (Calipers) – same as predicate	Diameter of indicator is less than diameter of rod passes	22 of 22 samples have indicator diameters less than their rod diameters – Pass
	Rod actuation force is too high due to the indicator diameter being too large	C	Handle with insert mechanical actuation – same as predicate ISO 7741:1986/(R)2017, Scissor Test Methods	No binding or impaired mechanical function passes	22 of 22 samples have no binding or mechanical functional impairments – Pass
2 use scissor	Poor cutting performance due to dull blade edge	C	Cut test simulation after simulated use and reprocessing – same as predicate ISO 7741:1986/(R)2017, Scissor Test Methods ASTM F1079-87, Surgical Scissors	After a single simulated surgery followed by cleaning and sterilization, shall pass cut test	15 of 15 samples pass cut test after a simulated surgery, cleaning and sterilization – Pass
	Residual Risk: User may use device after end of life. Risk is mitigated through End of Life Indicators in the Instructions for Use.				
Addition of indicator	Indicator scraping off	C	Visual inspection under magnification during mechanical testing – same as predicate ISO 10993-1:2009/(R)2013, Biocompatibility	No visual evidence of chipping, delamination, or cracking to the indicator passes	22 of 22 samples have no visual evidence of chipping, delamination or cracking to the indicator – Pass

Change (from predicate)	Risks	Risk Category (see chart below)	Verification Method / Standard Used	Acceptance Criteria	Results (Pass/Fail)
Addition of indicator	Indicator not attached to rod due to embrittlement from E-beam sterilization	C	Visual inspection after E-beam sterilization – same as predicate ISO 11137-1:2006/(R)2010, Radiation Sterilization	No visual evidence of chipping, delamination, or cracking to the indicator passes	22 of 22 samples have no visual evidence of chipping, delamination or cracking to the indicator – Pass
	Indicator not attached to rod due to damage during cleaning and sterilization at the hospital	C	Visual inspection after cleaning and sterilization – same as predicate ISO 17664:2017, Cleaning ISO 17665-1:2006/(R)2013, Steam Sterilization	No damage to the epoxy region passes	22 of 22 samples have no damage to the epoxy region – Pass
	Indicator delaminates from the rod or cracks due to damage from shipping or use	C	Visual inspection after ship testing – same as predicate ASTM D4169-16, Ship Testing	No visual evidence of chipping, delamination, or cracking to the indicator passes	22 of 22 samples have no visual evidence chipping, delamination, or cracking to the indicator – Pass
			Visual inspection after max dose irradiation, environmental conditioning, aging and ship testing – same as predicate ASTM D4169-16, Ship Testing	No visual evidence of damage (chipping, cracking, delamination) to the indicator passes	22 of 22 samples have no visual evidence chipping, delamination, or cracking to the indicator – Pass

Change (from predicate)	Risks	Risk Category (see chart below)	Verification Method / Standard Used	Acceptance Criteria	Results (Pass/Fail)
Addition of indicator	Indicator color does not permanently change to orange after cleaning and autoclaving due to using incorrect temperature/ humidity in autoclave	C	Visual inspection of indicator color change after environmental conditioning – same as predicate ISO 11607-1:2006/(R)2010, Sterile Barrier Systems	Color changes from black to orange passes	22 or 22 samples had color change from black to orange – Pass
	Residual Risk: User may use device if color change does not occur after cleaning and autoclaving. Risk is mitigated in the Sterilization Cautions in the Instructions for Use.				
	Indicator color permanently changes to orange during production or processing (including sterilization) due to E-beam sterilization	C	Visual inspection of indicator color change after max dose irradiation – same as predicate ISO 11137-1:2006/(R)2010, Radiation Sterilization	Color changes from black to orange passes	22 of 22 samples had color change from black to orange – Pass
	Indicator residue contacts patient	C	Visual inspection under magnification during mechanical testing – same as predicate ISO 10993-1:2009/(R)2013, Biocompatibility	No visual evidence of chipping, delamination, or cracking to the indicator passes	22 of 22 samples have no visual evidence of chipping, delamination, or cracking to the indicator – Pass
	Indicator changes to orange during transportation/storage due to product being exposed to extreme temperature/ humidity	C	Visual inspection after max dose irradiation, environmental conditioning, aging and ship testing – same as predicate ASTM D4169-16, Ship Testing	Indicator remains black after ship testing	22 of 22 samples have remained black after ship testing – Pass

Change (from predicate)	Risks	Risk Category (see chart below)	Verification Method / Standard Used	Acceptance Criteria	Results (Pass/Fail)
Stainless steel material modification 420/17-4PH to 303/17-4PH	Corrosion	C	Visual inspection after max dose irradiation, environmental conditioning, aging and ship testing – same as predicate ASTM A967-17, Stainless Steel Passivation	No visual evidence of corrosion or rust	22 of 22 samples have no evidence of corrosion or rust – Pass
	Embrittlement, breakage of assembly, leading to loss of function	C	Pouch drop testing IEC 60601-1 after max dose irradiation, environmental conditioning, aging and ship testing – same as predicate IEC 60601-1 edition 3.1, Electrical Safety	No bend in the rod	22 of 22 samples have no bend in their rod – Pass
	Embrittlement, breakage of assembly, leading to parts falling off in patient	C	Pouch drop testing IEC 60601-1 after max dose irradiation, environmental conditioning, aging and ship testing – same as predicate IEC 60601-1 edition 3.1, Electrical Safety	No bend in the rod	22 of 22 samples have no bend in their rod – Pass
	Intermittent power output at the tip	C	Direct measurement (resistance – multimeter) – same as predicate. IEC 60601-1 edition 3.1, Electrical Safety	Resistance is less than 5 ohms	22 of 22 samples have a resistance less than 5 ohms – Pass

Change (from predicate)	Risks	Risk Category (see chart below)	Verification Method / Standard Used	Acceptance Criteria	Results (Pass/Fail)
Rod diameter reduction	Impossible or difficult assembly into handle due to the rod being bent as a result of the reduced diameter for indicator application	C	Handle with insert mechanical actuation – same as predicate IEC 60601-1 edition 3.1, Electrical Safety Straightness inspection – same as predicate ASTM F2819-10, Rod Straightness ASTM D4169-16, Ship Testing	Any difficulty with actuation is a failure Rod gap meets straightness requirement	22 of 22 samples do not have any difficulty with actuation – Pass 22 of 22 Samples have a rod gap that meets straightness requirement – Pass
Sterility process change	Instrument becomes non-sterile during shipping	C	Instrument packaging sterile barrier seal integrity testing ISO 11607-2:2019, Sterile Barrier System ASTM F2096-11, Seal Integrity Bubble Test	The insert and sterile barrier shall withstand ship testing, with minimal cosmetic damage. After ship testing, the insert shall remain functional. The sterile barrier shall maintain product sterility	22 of 22 samples maintained a sterile barrier after ship testing – Pass
Reuse limitation	User misinterprets indicator's color change as verification of sterility	C	Correct Use of device based on indicator color and labeling in Quick Use Guide instructions (when received from OR) IEC 62366-1:2015, Medical Device Usability	Black color is correctly identified by Central Processing personnel Orange color correctly identified by Central Processing personnel	20 of 20 samples were correctly identified as black-Ok to reprocess – Pass 20 of 20 samples were correctly identified as orange-do not reprocess – Pass

Change (from predicate)	Risks	Risk Category (see chart below)	Verification Method / Standard Used	Acceptance Criteria	Results (Pass/Fail)
Reuse limitation	User does not dispose insert with orange indicator after second use	C	Correct Use of device based on indicator color and labeling in Quick Use Guide instructions (when received from OR) IEC 62366-1:2015, Medical Device Usability	Orange color correctly identified by Central Processing personnel	20 of 20 samples were correctly identified as orange-do not reprocess – Pass
	Poor cutting performance due to dull blade edge	C	Cut test simulation after simulated use and reprocessing – same as predicate ISO 7741:1986/(R)2017, Scissor Test Methods ASTM F1079-87, Surgical Scissors	After a single simulated surgery followed by cleaning and sterilization, shall pass cut test.	15 of 15 samples passed cut test after a simulated surgery, cleaning and sterilization – Pass
	Residual Risk: User may use device after end of life. Risk is mitigated through End of Life Indicators in the Instructions for Use.				

Equivalence Conclusion:

The AEM enTouch® 2X Scissor design changes do not introduce new safety or effectiveness concerns. The modification made do not affect the fundamental technological design of the subject device and there is no change to the Intended Use. Therefore, the subject device is substantially equivalent to the predicate device.