February 1, 2021

Human Xtensions Ltd.
% Randy Prebula
Partner
Hogan Lovells US LLP
Columbia Square 555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K203603
Trade/Device Name: Monopolar Hook
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, GEI
Dated: December 9, 2020
Received: December 9, 2020

Dear Randy Prebula:

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)*
K203603

Device Name
Monopolar Hook

Indications for Use *(Describe)*
The HandX is intended to assist in the control of Human Xtensions laparoscopic instruments including needle holder, grasper and monopolar instruments, for endoscopic manipulation of tissue, including grasping, approximation, ligation, suturing, cutting and/or coagulation, during laparoscopic surgical procedures.

The HandX monopolar instruments are connected by a standard cable to a standard electrosurgical power source. It is intended to be used by trained physicians in an operating room environment in accordance with its Instructions for Use.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Premarket Notification 510(k) Summary – K203603

The Company's 510(k) Summary is provided below.

Submitter:

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Date Prepared: February 1, 2021

Subject Device:

Device Name:	Monopolar Hook
Common Name:	Electrosurgical electrode
Device Classification Name:	Laparoscope, General & Plastic Surgery
Product Codes:	GCJ, GEI
Product Class:	Class II
Regulation Numbers:	21 CFR Parts 876.1500, 878.4400

Predicate Devices: HandX™, Human Xtensions (K173919)
SILS L-Hook, Covidien (K091869)

Device Description:

The Monopolar Hook is a single use sterile electrosurgical electrode for use with the HandX™ device. The Monopolar Hook is connected to the HandX device and transmits the HandX device motors' rotation in order to articulate the movement of the end effector of the Monopolar Hook. It is designed to address surgeons' needs relating to the application of monopolar diathermy for various surgical purposes.

The Monopolar Hook is connected to a standard electrosurgical unit via a standard generator cable.

Indications for Use:

The HandX is intended to assist in the control of Human Xtensions laparoscopic instruments including needle holder, grasper and monopolar instruments, for endoscopic manipulation of

tissue, including grasping, approximation, ligation, suturing, cutting and/or coagulation, during laparoscopic surgical procedures.

The HandX monopolar instruments are connected by a standard cable to a standard electrosurgical power source. It is intended to be used by trained physicians in an operating room environment in accordance with its Instructions for Use.

Contraindications:

The HandX is not intended for contraceptive coagulation of fallopian tissue, but may be used to achieve homeostasis following transaction of the fallopian tube.

Comparison of Technological Characteristics With the Predicate Devices:

The Monopolar Hook is substantially equivalent to the predicate devices, Human Xtensions' HandX (K173919) and Covidien's SILS L-Hook (K091869), in its intended use, contraindications, fundamental technology, sterilization method and general characteristics. The Monopolar Hook's electrosurgical characteristics were compared for usability and safety to the predicate device, the SILS L-Hook (K091869), under animal study. The similarities of the technological characteristics of the Monopolar Hook compared to the predicate devices are further outlined in Table 1, below.

Performance Data:

Biocompatibility testing, bench testing and a pre-clinical study were performed to support a determination of substantial equivalence. The results of the tests met acceptance criteria and demonstrated the safety and substantial equivalency of the Monopolar Hook. No safety or performance issues were raised during the testing.

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing:

The Monopolar Hook is categorized according to ISO 10993-1 as an externally communicating device in limited (≤24 hours) contact with tissue or bone. Per the categorization, the following endpoints were considered: cytotoxicity, sensitization, irritation, acute systemic toxicity, and material mediated pyrogenicity.

Electrical Safety and ElectroMagnetic Compatibility (EMC):

The Monopolar Hook was found to fully comply with the requirements of the IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, and IEC 60601-2-18, and IEC 60601-1-6.

Bench Testing:

The Monopolar Hook was subjected to bench testing to evaluate device performance and demonstrate that the design outputs meet the design input requirements and that the device is safe and effective for its intended use.

The verification bench testing included:

- Physical / Dimensional Inspection and Tip Measurements
- Functional Test

- Impedance Test
- DC Hipot-Ramp to Failure
- Generator Cable Pull Test
- Seal Test
- Sterile Barrier
- Mechanical Strength – Pull to Failure
- Passivation Verification - Corrosion Test
- Shaft's Insulation Integrity Test

All tests met the predefined acceptance criteria. The testing identified no new questions of safety and effectiveness.

Animal Study:

The Monopolar Hook was tested in a porcine model to evaluate the device's safety, functional performance, and usability. Device safety was assessed by a histopathology evaluation of slits performed by the Monopolar Hook in comparison to those performed by the predicate device (Covidien's, SILS L-Hook (K091869)). The Monopolar Hook performed similarly when compared to the predicate device.

Conclusion:

Based upon the intended use, technological characteristics, safety and performance testing, as well as comparison to the predicate devices, it can be concluded that the Monopolar Hook is substantially equivalent to its predicate devices. The minor differences between the subject and predicate devices do not raise any questions of safety and effectiveness.

Table 1 – Substantial Equivalence Table

Description	Human Xtensions Monopolar Hook	Human Xtensions HandX (K173919)	Covidien SILS L-Hook (K091869)	Substantial Equivalence
Product Code	GCJ GEI	GCJ	GCJ	Same
CFR	876.1500 878.4400	876.1500	876.1500	Same
Indications for Use	The HandX is intended to assist in the control of Human Xtensions laparoscopic instruments including needle holder, grasper and monopolar instruments, for endoscopic manipulation of tissue, including grasping, approximation, ligation, suturing, cutting and/or coagulation, during laparoscopic surgical procedures. The HandX monopolar instruments are connected by a standard cable to a standard electrosurgical power source. It is intended to be used by trained physicians in an operating room environment in accordance with its Instructions for Use.	The HX Device is intended to assist in the accurate control of HX laparoscopic Instruments including needle holder and grasper, for endoscopic manipulation of tissue, including grasping, approximation, ligation, suturing, during laparoscopic surgical procedures. It is intended to be used by trained physicians in an operating room environment, in accordance with its Instructions for Use.	The SILS™ L-Hook single use articulating hook with monopolar cautery has application in endoscopic, gynecological, and general abdominal and thoracic laparoscopic procedures. When connected by a standard cable to an electrosurgical power source, the device may be utilized for monopolar cautery.	Same
Contra-indications	Not intended for contraceptive coagulation of fallopian tissue, but may be used to achieve homeostasis following transaction of the fallopian tube.	N/A	Not intended for contraceptive coagulation of fallopian tissue, but may be used to achieve homeostasis following transaction of the fallopian tube.	Same

Technological Characteristics				
Specialty	Laparoscopic	Laparoscopic	Laparoscopic	Same
Mode of operation	Electromechanically operated, software controlled	Electromechanically operated, software controlled	Manual, hand maneuvered	Same
Insertion Method	Via Trocar	Via Trocar	Via Trocar	Same
Articulation	Yes	Yes	Yes	Same
Articulation range	0 to 85°	0 to 85°	0 to 85°	Same
Articulation locking feature	Yes	Yes	Yes	Same
Tip axial rotation feature	360°	360°	360°	Same
Shaft material	Stainless steel	Stainless steel	Stainless steel	Same
Electrosurgical Characteristics				
Application Technology	Monopolar	N/A	Monopolar	Same
Instrument type	Monopolar L-shaped hook	N/A	Monopolar L-shaped hook	Same
Tip length	5.7 mm to 6.5 mm	N/A	6.0 mm	Similar
Tip width	4.6 mm	N/A	4.7 mm	Similar
Material for electrode tip	Stainless steel	N/A	Stainless steel	Same
Energy activation	Generator foot pedal switch	N/A	Device finger-controlled switch	Both get energy from ESU; user controls the activation
Other Attributes				
Sterilization method	EtO	EtO	EtO	Same
Sterility assurance level	10-6	10-6	10-6	Same