May 10, 2023

Human Xtensions Ltd.
Hani Rauch
RA Manager
Meir Ariel 4
Netanya, 4250574
Israel

Re: K230491
Trade/Device Name: HandX™ Monopolar Scissors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ, GEI
Dated: February 5, 2023
Received: February 23, 2023

Dear Hani Rauch:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.05.10 08:22:23 -04'00'

Mark Trumbore
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

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
HandX(TM) Monopolar Scissors

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.

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K230491

Premarket Notification 510(k) Summary

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

Submitter:

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Date Prepared: May 7, 2023

Subject Device:

Device Name:	HandX™ Monopolar Scissors
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:	Monopolar Hook, Human Xtensions Ltd. (K203603)
Reference device:	ENDOPATH® Scissors, curved, with monopolar cautery, 5MM (K984240), Ethicon.

Device Description:

The Monopolar Scissors is a single-use, disposable, ETO sterilized instrument for use with the HandX™ device. The Monopolar Scissors is connected to the HandX and transmits the motors' rotations to articulate the movement of the Monopolar Scissors' end effector. It is designed to address surgeons' needs relating to the application of monopolar diathermy for various surgical purposes.

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.

Comparison of Technological Characteristics With the Predicate Devices:

The Monopolar Scissors is substantially equivalent to the predicate device, Human Xtensions' Monopolar Hook (K203603), in its intended use, contraindications, fundamental technology, packaging, sterilization method and general characteristics.

The main design characteristics of the instrument's effective length, diameter, materials and compatibility with commonly used 5mm trocars are similar to those of the Monopolar Hook.

The electrosurgical characteristics of the Monopolar Scissors are similar to its predicate device and similarly is connected to a standard Electrosurgical Unit (ESU) via a standard generator cable, which are generic Operating Room (OR) equipment.

Its dissection/cutting of organ/tissue function is comparable with the reference device Ethicon's ENDOPATH® 5MM Curved Scissors with Monopolar Cautery (K984240).

It can be concluded that the Monopolar Scissors is substantially equivalent to its predicate. No new questions of safety and effectiveness were raised.

Performance Data:

Bench testing, biocompatibility, electrical safety, human factors, and usability evaluations were performed to support a substantial equivalence determination. The results of the tests met the acceptance criteria and demonstrated the safety and substantial equivalency of the Monopolar Scissors. 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 Scissors is categorized according to ISO 10993-1 as an externally communicating device in limited (≤24 hours) contact with tissue or bone.

The materials of the Monopolar Scissors are similar to those of the previously cleared HandX™ instruments.

A full biological risk assessment for the Monopolar Scissors was performed according to the requirements of ISO 10993-1:2018, ISO 14971:2019 and FDA's guidance document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Per the categorization, the following endpoints were considered: cytotoxicity, sensitization, irritation, acute systemic toxicity, and material-mediated pyrogenicity.

Based upon the biological risk assessment and the results of biocompatibility testing performed on the device, it can be concluded that the device can be considered biocompatible for use as intended.

Electrical Safety and ElectroMagnetic Compatibility (EMC):

The Monopolar Scissors 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 Scissors was subjected to bench testing to evaluate its 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 the following:

- Instrument Dimensional Attribute
- Articulation Angle and Roll Range Measurement
- Roll and Grasp Torque Measurement Method
- Instrument Articulation latency
- Impedance Test
- Dielectric Strength
- Insulation Integrity test
- Generator Cable Compatibility with Extension Cables
- Proximal Seal Test
- Tip Integrity
- Deflection Integrity
- Cutting Integrity
- Performance Test (instrument integrity following simulated use)
- Human Factors Summative Evaluation
- Human Factors Labeling Validation
- Instrument Corrosion Test

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

Performance Testing – Animal

The HandX Monopolar Scissors was tested in a swine model to evaluate the device's safety, functional performance and usability. The evaluation was executed by performing various surgical tasks, using both the subject device and the reference device, by qualified personnel with appropriate experience, followed by questionnaires filled out by the participants.

The device's safety was assessed by thermal damage evaluation using temperature probes and histopathology evaluation according to FDA Guidance *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff*. Temperature and histopathology evaluations were performed following slits formation on porcine tissue. Slits were performed by the Monopolar Scissors as compared to the reference device ENDOPATH® Scissors (curved, with monopolar cautery, 5MM) in various working modes (pure cut, blend cut, spray and coagulation) and in different energy levels.

It can be concluded that the Monopolar Scissors instrument passed all the per-defined acceptance criteria for safety, performance and usability.

Conclusion:

Based upon the intended use, indications, technological characteristics and performance testing, it can be concluded that the Monopolar Scissors is substantially equivalent to its predicate device. The differences between the subject and predicate devices do not raise any questions about safety and effectiveness.