January 12, 2023

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

Re: K222011
Trade/Device Name: HandX Instrument - Monopolar Spatula
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, GEI
Dated: December 14, 2022
Received: December 14, 2022

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,

Colin K. Chen -S

for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222011

Device Name
HandX™ Monopolar Spatula

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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510(k) SUMMARY

Human Xtensions Ltd.'s HandX

Submitter:

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Date Prepared:

January 11, 2023

Subject Device:

Device Name:	HandX™ Monopolar Spatula
Common Name:	Electrosurgical electrode
Classification Name:	Laparoscope, General & Plastic Surgery
Product Codes:	GCJ, GEI
Product Class:	Class II
Regulation Number:	21 CFR Part 876.1500 21 CFR Part 878.4400
Predicate Device:	Monopolar Hook, Human Xtensions (K203603)
Reference Device:	ENDOPATH Electrosurgery PROBE PLUS II (K160128)

Intended Use / 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.

Device Description

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

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

Comparison of Technological Characteristics With Predicate Device:
The Monopolar Spatula is substantially equivalent to the predicate device, Human Xtensions' HandX™ Monopolar Hook (K203603), in its intended use, contraindications, fundamental technology, mechanical performance characteristics and sterilization method. The Monopolar Spatula is an alternative electrode for the Monopolar Hook for surgical tasks that require monopolar cutting and/or coagulation during surgeries. It differs from the Monopolar Hook only in the end effector's tip shape and material; all other components and assembly configuration are identical.

The electrical functionality of the Monopolar Spatula is equivalent to that of the cleared Monopolar Hook. The Monopolar Spatula's usability and safety aspects were compared to the predicate device in Human Factors Summative Evaluation, bench tests, and in vivo testing.

Performance Data

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

Biocompatibility Testing:
The Monopolar Spatula is categorized per ISO 10993-1 as an externally communicating device in limited (≤24 hours) contact with tissue or bone. Accordingly, the following endpoints were considered: cytotoxicity, sensitization, irritation, acute systemic toxicity, and material mediated pyrogenicity. The device was deemed to pose a negligible risk of toxicity and is considered to have met the requirements of ISO 10993-1:2018 and FDA's corresponding guidance and to be safe for use as intended.

Electrical Safety and Electromagnetic Compatibility (EMC):
The Monopolar Spatula was found to fully comply with the requirements of IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, IEC 60601-2-18, and IEC 60601-1-6.

Bench Testing:
Bench testing was conducted to evaluate device performance and to 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:

- Verification of Dimensional attributes
- Seal Test
- Tip Pull to Failure

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

Thermal Effects Testing:
Ex-vivo and *in-vivo* studies were conducted using a porcine model to evaluate the thermal behavior and the lateral thermal spread of the Monopolar Spatula compared to its predicate and reference

devices. The results supported the substantially equivalent thermal behavior of the Monopolar Spatula compared to the predicate and reference devices.

Human Factors/Usability:
A summative evaluation study (per IEC 62366-1) confirmed that the device can be used safely and effectively in accordance with its labeling.

Conclusion

Based upon the intended use, technological characteristics, safety and performance testing, as well as comparison to the predicate device, it can be concluded that the HandX™ Monopolar Spatula is substantially equivalent to its predicate device. The minor differences between the subject and predicate device do not raise any different questions of safety and effectiveness, and the design controls and data collected ensure no adverse impact on safety or effectiveness.