September 13, 2021

Human Xtensions Ltd.
% Randy Prebula
Partner
Hogan Lovells US LLP
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Washington, District of Columbia 20004

Re: K212214
Trade/Device Name: HandX
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, NAY, GEI
Dated: July 15, 2021
Received: July 15, 2021

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

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 on last page

510(k) Number *(if known)*

K212214

Device Name

HandX

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) SUMMARY

Human Xtensions Ltd.'s HandX

Submitter:

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Date Prepared: September 9, 2021

Subject Device:

Device Name:	HandX
Common Name:	HandX
Classification Name:	Laparoscope, General & Plastic Surgery
Product Codes:	GCJ, NAY, GEI
Product Class:	Class II
Regulation Number:	21 CFR 876.1500, 876.4400

Predicate Devices: HX Device, Human Xtensions (K173919)
Monopolar Hook, Human Xtensions (K203603)

Purpose of the Special 510(k) Notice

The HandX is a modification to the prior versions of the device that were cleared under K173919 (HX Device) and K203603 (Monopolar Hook).

Intended 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 Human Xtensions HandX is a handheld powered laparoscopic device. The HandX enables, by its attached instruments Grasper, Needle Holder and Monopolar Hook, the surgeon to perform a variety

of minimally invasive surgeries. As the device is controlled by the surgeon's hand, it acts as a “surgeon's hand extension,” enhancing maneuverability and control.

The HandX device is electromechanically controlled and includes both hardware and software. The device is comprised of two main parts: the Handpiece and the Instrument. The Handpiece consists of a reusable Control Interface (CI) handle and Handpiece Body that translates the surgeon's maneuvers and movements of their hands by means of control buttons to the instrument-articulating tip. The tip moves according to the CI’s direction. Prior to use, a set of Power Cable, Finger Pads, Arc and Spacer are assembled on the Handpiece and the CI, and the Handpiece is covered with a standard sterile cover (not provided with the HandX device). After use, the Instrument is disposed of, and the Handpiece is cleaned and disinfected per specifications in the Instructions for Use.

The HandX has nearly identical technological characteristics and principles of operation as the combined predicate devices. The only notable difference between the subject HandX and the combined predicates is the addition of the inverted control mode; whereas the predicate devices’ software included only direct control (“Ro-bo style”) for the CI, the subject HandX provides direct control as well as inverted control (“La-pro style”) as an additional, optional CI control mode. This difference does not raise new questions of safety or effectiveness, as it does not alter the fundamental therapeutic purpose of the device or its basic principles of operation (users control the inserted instruments in the same manner, just using one or another set of vectors). The new mode also does not change the key metrics for evaluating device safety and performance, and is supported by successful usability testing (as noted below).

Performance Data

The company conducted usability testing of the inverted control mode in line with IEC 62366-1:2015 and ANSI/AAMI HE75:2009/(R)2018, as well as FDA’s 2016 guidance document. The testing demonstrated that potential safety-critical consequences are reasonably mitigated by the design of the inverted control mode and its associated instructional materials, which were clear and easy to understand by both novel and experienced users.

Conclusion

Based on the intended use, technological characteristics, principles of operation, and usability testing, it can be concluded that the HandX is substantially equivalent to its predicate devices.

Substantial Equivalence (SE) Table

	Human Xtensions HandX (Modified Device)	Human Extensions HX Device (K173919)	Human Xtensions Monopolar Hook (K203603)	Comparison of Subject to Predicates
Intended Use	Intended for use in various laparoscopic surgeries to perform a variety of surgical functions, including grasping, approximation, ligation, suturing, cutting and/or coagulation	Intended for use in various laparoscopic surgeries to perform a variety of surgical functions, including grasping, approximation, ligation, and suturing.	Intended for use in various laparoscopic surgeries to perform a variety of surgical functions, including grasping, approximation, ligation, suturing, cutting and/or coagulation	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 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.	Same – Identical to K203603; only adds Monopolar Hook to indications cleared in K173919
Specialty	Laparoscopic			Same
Mode of Operation	Electromechanically operated, software controlled			Same
Components	Handpiece and compatible instruments (Grasper, Needle Holder, Monopolar Hook); Arc, Pads, Spacer, Power Cable	Handpiece and compatible instruments (Grasper, Needle Holder); Arc, Pads, Spacer, Power Cable	Instrument compatible with HandX Handpiece (Monopolar Hook)	Same as combined predicates
Grasper Type	Fenestrated		N/A*	Same as K173919
Needle Holder Type	Straight – Single Action		N/A*	Same as K173919
Electrosurgical Instrument Type	Monopolar hook	N/A	Monopolar hook	Same as K203603
Articulation	Yes	Yes	Yes	Same
Control Interface Mode	Direct control and inverted control	Direct control	N/A*	Adds inverted control mode
Single Use / Reusable	Handpiece: reusable Instruments: single use	Handpiece: reusable Instruments: single use	Instrument: single use	Same as combined predicates
Sterile Components	Instruments, Arc, Finger Pads, Spacer, and Power Cable	Instruments, Arc, Finger Pads, Spacer and Power Cable	Instrument (does not include other components)	Same as K173919

*The K203603 filing only included the Monopolar Hook and did not re-include the entire system.