June 5, 2023

Human Xtensions Ltd.
Orit Yaniv
VP QA/RA
Human Xtensions Ltd.
Grand Netter Building
4 Meir Ariel Street
Netanya, 4250574, Israel
Telephone: + (972) 77 36 30 300
Email: orit@human-x.com

Re: K223718
Trade/Device Name: HandX™ Self-Righting Needle Holder
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 11, 2022
Received: December 12, 2022

Dear Orit Yaniv:

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: 2023.06.05 11:23:01 -04'00'

Mark Trumbore, 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)*

Device Name
HandX(TM) Self-Righting Needle Holder

Indications for Use *(Describe)*

The HandX is intended to assist in the control of Human Xtensions 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.

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

Submitter:

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Date Prepared: May 24, 2023

Subject Device:

Trade/Device Name:	HandX™ Self-Righting Needle Holder
Common/Usual Name:	Articulated Laparoscopic Instruments
Device Classification Name:	Endoscope and Accessories
Product Codes:	GCJ
Product Class:	Class II
Regulation Numbers:	21 CFR Parts 876.1500

Predicate Devices: HX Device, Needle Holder, Human Xtensions Ltd. (K173919)

Reference Device: ENDOPATH® Self-Righting Needle Holder (K972679), Ethicon. Used as a reference device for Self-Righting function.

Device Description:

The Self-Righting Needle Holder is a single-use, disposable, ETO sterilized instrument for use with the HandX™ device. The Self-Righting Needle Holder is connected to the HandX™ and transmits the motors' rotations to articulate the movement of the Self-Righting Needle Holder's end effector. Self-Righting Needle Holder orients the suturing needle vertically to 90° mounting. It is designed to address the surgeons' needs relating to suturing for various surgical purposes.

Indications for Use:

The HandX™ is intended to assist in the control of Human Xtensions 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.

Comparison of Technological Characteristics with the Predicate Devices:

The Self-Righting Needle Holder is substantially equivalent to the predicate device, Human Xtensions' HX Device (K173919), in its intended use, contraindications, fundamental technology, packaging, sterilization method and general characteristics. Its Self-Righting function is the same as Ethicon's ENDOPATH® Self-Righting Needle Holder (K972679).

A summary of the technological characteristics of the Self-Righting Needle Holder device in comparison to those of the predicate device and reference device is presented in the table below.

Description	HandX™ Self-Righting Needle Holder (Subject device)	HX Device, Needle Holder (Predicate device)	ENDOPATH® Self-Righting Needle Holder (Reference device)
510(k) Number	K223718	K173919	K972679
Product Code	GCJ	GCJ	GAT
CFR	21 CFR 876.1500	21 CFR 876.1500	21 CFR 876.4730
Indications for Use	The HandX™ is intended to assist in the control of Human Xtensions 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 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 ENDOPATH® Endoscopic Tissue Fastening System (ETFS) is intended for use in minimally invasive surgical applications where soft tissue is being approximated with the interrupted stitches.
Contra-indications	This device is intended for use only as indicated.	This device is intended for use only as indicated.	NA
Specialty	Laparoscopic	Laparoscopic	Minimally invasive surgical application
Mode of operation	Electromechanically operated, software controlled	Electromechanically operated, software controlled	Manually
Insertion Method	Via 5mm Trocar	Via 5mm Trocar	Via 5mm Trocar
Articulation	Yes	Yes	No

Description	HandX™ Self-Righting Needle Holder (Subject device)	HX Device, Needle Holder (Predicate device)	ENDOPATH® Self-Righting Needle Holder (Reference device)
Articulation range	0 to 80°±10°	0 to 85°±5°	NA
Articulation locking feature	Yes	Yes	NA
Tip axial rotation feature	360°	360°	NA
Shaft material	Stainless steel	Stainless steel	Stainless steel
Instrument type	Self-Righting Needle Holder	Needle Holder	Self-Righting Needle Holder
Material for electrode tip	Stainless steel	Stainless steel	Stainless steel
Shaft length	330 mm ±0.1 mm	330 mm ±0.1 mm	NA
Shaft diameter	5.5 mm ±0.2 mm	5.5 mm ±0.1 mm	NA
Single Use / Reusable	Single use instrument	Single use instrument	Re-usable
Packaging	Blister	Blister	NA
Provided sterilized	Yes	Yes	NA
Sterilization method	EtO	EtO	NA
Sterility assurance level	10^{-6}	10^{-6}	NA

It can be concluded that the Self-Righting Needle Holder is substantially equivalent to its predicate. No new questions of safety and effectiveness were raised.

Performance Data:

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

Biocompatibility Testing:

The materials of the Self-Righting Needle Holder are identical to those of the predicate device. The predicate device has been tested and is considered biocompatible for its intended use. Therefore, from a biocompatibility and toxicological perspective, the device remains unchanged, and no additional

testing is required for the HandX™ Self-righting Needle Holder device since only the jaws geometry of the needle was changed.

Bench Testing:

The Self-Righting Needle Holder 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 is described in the table below, all tests met the predefined acceptance criteria. The testing identified no new questions of safety and effectiveness.

Test	Test Summary	Conclusions
Self-Righting Needle Holder Angle Test	The purpose of the test was to measure the subject device articulation angles while connected to the HandX device.	The subject device tip articulation ability is comparable to the predicate device.
SRNH instrument Dimensional Attribute	The purpose of the test was to confirm the subject device dimensions to the specifications	The subject device dimensions are within the defined requirements.
SRNH Suture Holding Force	The purpose of the test was to measure the subject device suture holding force.	The subject device suture holding force withstands the defined requirements as the predicate device.
SRNH Needle Pulling Moment	The purpose of this test was to determine whether the subject device maintains the needle in place under external moment.	The subject device complies with the needle pulling moment requirement.
SRNH Needle Holding Force	The purpose of this test was to determine whether the subject device maintains the needle in place under external force.	The subject device complies with the needle holder holding force requirement
SRNH Needle Righting	The purpose of the test was to verify the subject device transition ability of a surgical needle to a right position.	The subject device demonstrated transition ability of surgical needles to right position, thus met the predefined requirements.

Conclusion:

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