March 20, 2018

Human Extensions Ltd.
% Orly Maor
Regulatory Consultant
Orly Maor
25 Sirkin Street
Kfar Saba, Israel 44421

Re: K173919
Trade/Device Name: HX Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, NAY
Dated: February 28, 2018
Received: March 5, 2018

Dear Orly Maor:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K173919

Device Name
HX Device

Indications for Use *(Describe)*

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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HumanExtensions

Traditional Premarket Notification Submission – 510(k)

HX Device

510(k) Number K173919/S001

Date Prepared: March 17, 2018

I. SUBMITTER

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II. DEVICE

Name of Device: HX Device
Common or Usual Name: HX Device
Classification Name: Laparoscope, General & Plastic Surgery (Regulation 876.1500)
Regulatory Class: II
Product Code: GCJ; NAY
Panel: General & Plastic Surgery

III. PREDICATE DEVICE

Human Extensions Ltd. believes that the HX Device is substantially equivalent to the following predicate devices:

- Cambridge Endoscopic Devices Inc. PureWrist™ cleated under K061425
- Aesculap's Sovereign® mini system cleared under K123102

In addition, additional device the daVinci Surgical System (Intuitive Surgical Inc.) cleared under several clearances K131861 (product codes: NAY) and K170875 (product codes: NAY, GCJ) is being used as a reference device in respect to its technology and in particular its using sterile drape cover.

Traditional Premarket Notification Submission – 510(k)

HX Device

510(k) Number K173919/S001

IV. DEVICE DESCRIPTION

The Human Extensions HX Device is a hand held powered laparoscopic device. The device enables, by its attached instruments grasper and needle holder, 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 HX Device is electromechanically controlled and includes both hardware and software and comprises of two major parts, the Handpiece and the Instrument.

The HX Device Handpiece consists of a reusable Control Interface (CI) handle held by the surgeon and a Handpiece Body that translates the surgeon's maneuvers and movements of their hands by means of control buttons to the instrument-articulating tip (grasper/needle holder). Prior to use, a set of single use, disposable, sterile Power Cable, Arc, Finger Pads, and strap-adapting Spacer are assembled on the Handpiece and the CI unit.

In addition, prior to use, the Handpiece is covered with a standard, sterile cover (e.g., endoscopic camera cover) of at least 8.5 cm inner diameter. The sterile cover is not provided with the HX device.

After each use, the Handpiece is cleaned and disinfected according to the specifications detailed in the Instructions For Use.

V. INDICATIONS 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Human Extensions believes that the HX Device has the similar intended use and indications for use as the predicate devices and the reference device the daVinci system. The instruments principles of operation and functionality characteristics are similar as well.

The HX Device Instrument, like the predicate, is inserted through a trocar to assist in procedures in which tissue grasping and suturing is needed under direct visualization. The Instruments for both devices have articulating design at the distal tip that mimics the human hand. The instruments of the HX Device are needle holder and grasper and performed the same tasks as the predicate devices.

Specifically, the use of electromechanical control systems, end-effectors, and degree of mechanical articulation, manipulation and mode of operation of the predicate device and the HX device are comparable.

The daVinci reference device and the HX Device share the same risk/benefit profile in regards to the cover (sterile drape) and cleaning and disinfection method.
Based on the above analysis, Human Extensions Ltd. believes that the HX Device is substantially equivalent to the legally marketed predicate devices.

VII. PERFORMANCE DATA

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

- **Risk analysis** per ISO 14971
- **Biocompatibility testing**
  An evaluation of biocompatibility was performed in compliance with ISO 10993. All tests were completed and passed.
- **Sterilization, Cleaning, Packaging and Shelf Life Testing**
  Sterilization validation testing of the single use parts was performed to demonstrate compliance with ISO 11135-1. The handle was validated for cleaning and re-use. In addition, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.
- **Bench Testing**
  Bench testing included the following:
  - HX Device Performance Evaluation
  - Instrument Corrosion Test
  - Needle Holder Instrument Reliability Evaluation
  - Arc and Pads Reliability Evaluation
  - Dimensional Attributes Verification
  - Tissue Grasping Force Test
  - Needle Holding Strength
  - Grasper Instrument Reliability Evaluation
  - Device Motion Performance Test
  - Motor Drive Chain Durability
  - Liquid Permeability (Sterile Cover Non-Permeability Evaluation Report)
  - Bacterial Permeability (aseptic barrier validation of a standard sterile covered HX Device Handpiece)

  All tests met the predefined acceptance criteria.

- **Animal Study**
  GLP Animal Study was performed by several users. Devices performed well without malfunction to users' satisfaction. The users were able to perform tissue manipulation tasks such as grasping different tissues, and to perform continues or interrupted sutures tasks. The test met the predefined acceptance criteria.

- **Software Validation**
  Software verification and validation tests were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- **Electrical Safely and EMC**
  Electrical Safety per IEC 60601-1 and Electromagnetic Compatibility (EMC) per IEC 60601-1-2 were conducted on the HX Device.

VIII. CONCLUSIONS

The HX Device has the same intended use as the predicate devices. The principal features of the device that were described, as well as the tests provided, show that the minor differences in the device characteristics between the subject device and predicate device do not raise any new questions of safety or effectiveness.

Performance data, GLP animal study and software validation demonstrates that the HX Device performs as intended and, in a manner, that is substantially equivalent to the predicate.

Therefore, the device may be found substantially equivalent.