January 29, 2021

Dex Surgical
Guillaume Noury
CEO
3 Rue Des Petits Ruisseaux
Verrieres Le Buisson, 91370 France

Re: K191878
Trade/Device Name: DEX Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 28, 2020
Received: December 28, 2020

Dear Guillaume Noury:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191878

Device Name
DEX Device

Indications for Use *(Describe)*

The DEX device laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, suturing, transection and electro-cauterization of tissues.

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.

510(K) SUMMARY

I. SUBMITTER

Dex Surgical
3 rue des petits ruisseaux
91370 VERRIERES LE BUISSON FRANCE

Contact person : Guillaume Noury

Date prepared 27 january, 2021

II. DEVICE

Trade Name : DEX Device
Common name : Articulated Laparoscopic Instruments
Classification Name : Endoscopic instruments and Accessories`
CFR section : 878.4400
Regulatory Class : II
Product Code : Classification product code: GEI

III. PREDICATE DEVICE

Predicate device used : K061425, Pure wrist
A reference device has been used : K173919, HX device

IV. DEVICE DESCRIPTION

The DEX Device consists of an electro-mechanical system designed for surgeon to perform minimal invasive surgeries: laparoscopic surgery. The surgeon will use the system in a similar way than any laparoscopic instruments and remains in contact with the patient. The surgeon will positioned himself like in any classic laparoscopic procedure, standing in the sterile field close to the patient: Same installation, trocars,

endoscopic camera, suction, ESU for monopolar, needles, operating table, instruments, procedure.

The device consists of a Console, a Control handle and different Arms (instruments); and accessories. The Console hosts the software and the power unit. The control handle is comprised of an ergonomic hand piece that can turn on its own axis thanks to the comfort joint. The control handle has command buttons that activate the different degrees of freedom or the Arm. Different arms can be connected on the control handle.
Arms consists in a distal articulation that allows the tip (scissors, needle holder, forceps or Hook) to tilt, rotate and open-close. The arms and the control handle are reusable and autoclavable. The scissors, the dissector (Maryland) and the hook supports electrocautery monopolar energy after connecting the standard monopolar cable between DEX device and an ESU compliant with IEC 60601-2-2; After installed the neutral electrode; The user can control the cautery effect by pressing on the foot pedal switch provided with the ESU.

Associated acessories includes : sleeves

V. INDICATION FOR USE

The DEX device laparoscopic instruments have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection, suturing, transection and electro-cauterization of tissues.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

DEX Surgical believes that the DEX device has the similar intended use and indications for use as the predicate. The instruments principles of operation and functionality characteristics are similar. Both devices are Hand Held, with a range of different instruments with multiple distal mobility and have application in a variety of minimally invasive procedures to facilitate grasping, mobilization, dissection and transection of tissues. Like the predicate DEX device, intended to be used in laparoscopic surgery, by laparoscopic surgeons for manipulation soft tissues. The surgical procedure stills the

same with DEX than classical laparoscopy. DEX is inserted through a trocar to assist in laparoscopic procedures.
Like the predicate DEX device is an active electrode compatible to be used with an HF generator compliant with IEC 60601-2-2. Both device equipped with monopolar cautery connection and can be used to cauterize tissues when the instrument is attached to standard cautery cable, neutral electrode and electrosurgical unit.

Summary of the same technological elements:

- Hand held laparoscopic instrument
- Range of instruments: dissector, scissors, needle holder, hook
- Inserted threw trocars, same installation
- Distal mobility of the tip
- Wrist and finger control of the distal movement
- Monopolar active electrode when connected to an ESU with a 4 mm cable socket

The following difference exists between the subject and the predicate device.

- Diameter of the instrument 8-10 mm
- Reusable and autoclavable
- Electromechanical control of the movement
- Sleeve (tip cover)

The reference device and DEX device are both laparoscopic hand held devices too; the surgeon is in the same position than with any laparoscopic device. Both devices are "co-manipulated devices" and have an articulation at the tip of the instruments that is commanded by the surgeon’s wrist and/or the surgeon’s fingers. Both devices use software to allow a motorized motion of tip and have an electromechanical control of the movement

VII. Performance data

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

Biocompatibility testing

The aim of this biological evaluation is to provide the biological safety of the DEX Device. It was done according to:

- Standard ISO 10993-1: 2018 "Biological evaluation of medical devices",
- Other standards of the 10993 series, and
- FDA Guidance for Industry and FDA Staff "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", issued on June 2016.

The following tests have been conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogenecity

The DEX device is considered tissue contacting for a duration of less that 24 hours.

A large majority of materials of the applied part have been chosen from the stainless material standards for surgical instrumentation:

- ASTM F138
- ASTM F1058
- ASTM F899-12b
- ISO 7153-1: Surgical instruments -- Materials -- Part 1: Metals

Electrical safety and electromagnetic compatibility (EMC)

Electrical Safety and EMC testing were conducted on DEX device. Tested and validated by an independent laboratory, in compliance with IEC 60601-1:2012 and IEC 60601-2-2: 2017.

Electromagnetic compatibility was tested and validated by an independent laboratory, in compliance with IEC 60601-1-2 Ed4.0 (2014).

Bench test

> Needle Holder reliability evaluation

> Scissor reliability evaluation

> Grasper reliability evaluation

> Control handle and motors reliability evaluation

> Sleeves reliability evaluation

> Shaft Insulation

> System testing : monopolar energy (animal test)

> Shaft insulation

> Thermal spread of Dex device vs Predicate device

> Transport and packaging testing

The durability and the safety of DEX device were evaluated with different tests in real conditions or in simulated conditions. These studies demonstrate that the DEX device can be safely used for the intended use defined.

Cleaning and sterilization validation, reprocessing

Steam sterilization was tested and validated by an independent laboratory, in compliance with ISO 17664 – ISO 17665 Standards and AAMI TIR 12 Technical Report. Cleaning procedures were tested and validated by an independent laboratory following AAMI TIR12 and AAMI TIR30.

Software validation

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005) and IEC 62304:2006 (First Edition) + A1:2015 Medical device software - Software life cycle processes.

Clinical study

No clinical studies have been conducted.

Usability

The DEX Device usability was assessed and found to be safe and effective for its intended uses, by the intended users, in its intended use environment.

ACCORDING TO THE STANDARDS IEC 60601-1-6:2010 (Third Edition) + A1:2013 and EN 60601-1-6:2010 +A1:2015.

Thermal effect

Thermal Spread of DEX monopolar arm has been compared to the predicate device.
The DEX device thermal effect in monopolar mode is equivalent to the thermal effect of the predicate device. The effect on different types of tissues gives comparable affected surface with usual and identical settings when use with a legally marketed ESU. Histomorphometric analysis on fresh tissues demonstrated the same characteristics of thermal spread in monopolar mode (CUT and COAG) between Dex Device and the Predicate Device.

Simulated use

DEX invasive parts have performed 40 simulated uses including fresh tissues interactions, cauterization, cleaning, lubrication and autoclave for each cycle.
DEX device monopolar arms after have successfully passed the 40 simulated uses:
No damage, cracks, corrosion and associated risks have been identified after the whole 40 cycles tested.

VIII. Conclusion

The DEX Device has the same intended use than the predicate device. The features comparison review of the subject device and the tests provided show that the technological differences between the DEX Device and the predicate devices do not raise any new question of safety and effectiveness.

The whole performance data analysis demonstrates that the subject device performs as intended and that it is substantially equivalent to the predicate device.