DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2017

Dextera Surgical, Inc.
Ms. Pamela Segale
Consulting VP, Regulatory Affairs
900 Saginaw Drive
Redwood City, CA 94063

Re: K171561
Trade/Device Name: Dextera MicroCutter 30 Blue Reload, Dextera MicroCutter 30 Curved Tip Blue Reload, Dextera MicroCutter 30 White Reload, Dextera MicroCutter 30 Curved Tip White Reload
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: May 27, 2017
Received: May 30, 2017

Dear Ms. Segale:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171561

Device Name
MicroCutter 30 Blue Reload, MicroCutter 30 Curved Tip Blue Reload, MicroCutter 30 White Reload, MicroCutter 30 Curved Tip White Reload, Dextera MicroCutter 5/80 Stapler

Indications for Use *(Describe)*
The MicroCutter 5/80 Stapler and MicroCutter 30 White, Blue, and Curved Tip White and Blue Reloads are intended for transection and resection in multiple open or minimally invasive urologic, thoracic, and pediatric surgical procedures, as well as application for transection, resection, and/or creation of anastomoses in the small and large intestine, and the transection of the appendix.

The MicroCutter 5/80 Stapler and MicroCutter 30 White and Curved Tip White Reloads may additionally be used in conjunction with open solid organ parenchymal dissection techniques on veins 4-5 mm in diameter and arteries 3-7 mm in diameter.

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

A. Date Prepared

August 25, 2017

B. 510(k) Owner

Dextera Surgical Inc.
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Redwood City, California 94063
Phone: 650-364-9975
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C. Contact Person

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Consulting VP, Regulatory Affairs
(650) 331-7131 (office)
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D. Device Information

Trade name:
MicroCutter 30 Blue Reload,
MicroCutter 30 Curved Tip Blue Reload,
MicroCutter 30 White Reload, and
MicroCutter 30 Curved Tip White Reload

Common name: Staple
Classification Name: Implantable staple
Regulation Number: 21 CFR §878.4750
Product Code: GDW

E. Marketed Predicate Devices

Ethicon ENDOPATH® ETS-Flex45 Endoscopic Articulating Linear Cutters and (Reloads) (K070887)

Reference Devices
MicroCutter 30 Blue Reload, MicroCutter 30 Curved Tip Blue Reload, MicroCutter 30 White Reload and MicroCutter 30 Curved Tip White Reload used with the MicroCutter 5/80 Stapler (K151081 and K161137)

F. Device Description

Each MicroCutter 30 Reload contains two double rows of 316L stainless steel staples. The size of the MicroCutter 30 Blue Reload and MicroCutter 30 Curved Tip Blue Reload staple is compatible with tissue that can be easily compressed to 1.5mm. The size of the MicroCutter30 White Reload and MicroCutter 30 Curved Tip White Reload staple is compatible with tissue that can be easily compressed to 1.0mm. If tissue cannot comfortably compress to the Maximum Tissue Thickness listed for each reload, or easily compresses to less than the Maximum Tissue Thickness listed for each reload, the tissue

is contraindicated as it may be too thick or too thin for the selected staple size. The cut length of the staple line is 28.0mm (1.10in) and the staple line length is 30mm long. The MicroCutter 30 Reloads are deployed using the Dextera MicroCutter 5/80™ Stapler. The MicroCutter 5/80 Stapler is a single patient use stapler that delivers two, double staggered rows of 316L stainless steel staples while simultaneously transecting tissue between staple rows.

G. Indications for Use

The MicroCutter 5/80 Stapler and MicroCutter 30 White, Blue, and Curved Tip White and Blue Reloads are intended for transection and resection in multiple open or minimally invasive urologic, thoracic, and pediatric surgical procedures, as well as application for transection, resection, and/or creation of anastomoses in the small and large intestine, and the transection of the appendix.

The MicroCutter 5/80 Stapler and MicroCutter 30 White and Curved Tip White Reloads may additionally be used in conjunction with open solid organ parenchymal dissection techniques on veins 4-5 mm in diameter and arteries 3-7 mm in diameter.

H. Comparison to Predicate Device

A comparison of the subject devices to the predicate devices demonstrates that the devices have the same intended use, which is to transect, resect and create anastomoses in patients during surgery in a variety of surgical procedures including urologic, thoracic, pediatric, and intestinal surgery. Additionally, they have the same mechanism of action and similar technologies given both the subject and the predicate devices achieve their intended use by means of cartridge based metal staples that are delivered using stapling devices.

Chronic animal studies, previously submitted by Dextera Surgical (K151081), were conducted in which unilateral nephrectomies and unilateral lobectomies were performed comparing the Dextera Surgical subject staple and the predicate Ethicon staple. The endpoints of the studies were met with no demonstrable differences noted between the subject devices and the predicate devices. Non-clinical performance data was also previously submitted (K151081) in which the Dextera Surgical subject staple and the Ethicon predicate staple were compared during Tissue Burst Pressure testing in porcine arteries. The test data demonstrated the subject devices to be substantially equivalent to the predicate devices.

I. Performance Data

Non-Clinical Performance Data

Functional performance testing was conducted using the subject staple and the predicate staple on porcine veins during Tissue Burst Pressure testing. The testing simulated transection of vessels as may be encountered during surgery on solid organs. The results demonstrated the subject devices to be substantially equivalent to the predicate devices.

J. Conclusion

The subject devices and the predicate devices have the same intended use and similar indications for use. Additionally, the subject devices and the predicate devices have the same mechanism of action and utilize similar technologies. Functional performance testing (Tissue Burst Pressure) was conducted with the results demonstrating the subject

devices to be substantially equivalent to the predicate devices. Thus, based on the data and the comparison of the devices, the subject devices are substantially equivalent to the predicate devices.