December 18, 2019

Fengh Medical Co., Ltd.
Jiao Liu
RA Manager
D3 No.6 Dongsheng West Road, Jiangyin National
High-tech Zone
Jiangyin, 214437 Cn

Re: K182476
Trade/Device Name: Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: November 13, 2019
Received: November 18, 2019

Dear Jiao Liu:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*
K182476

Device Name
Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads，Model include 30mm series，45mm series and 60mm series

Indications for Use *(Describe)*
The Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general abdominal, gynecologic, thoracic, and pediatric surgical procedures.

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

(As Required by 21 CFR 807.92)

1. Date Prepared [21 CFR 807.92(a)(1)]

Jan 29th, 2019

2. Submitter's Information [21 CFR 807.92(a)(1)]

Company Name: Fengh Medical Co., Ltd.
Company Address: D3 No.6 Dongsheng West Road, Jiangyin National High-tech Zone, 214437 Jiangsu, China
Contact Person: Jiao Liu
Phone: 0086-13815132106
Email: Jiao.liu@fenghmedical.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads，Model include 30mm series，45mm series and 60mm series
Common Name: Implantable staple
Product Code: GDW
Regulation Number: 21 CFR 878.4750
Device Class: II

4. Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]

The identification of predicates within this submission is as follow:

Manufacturer: Ethicon Endo-Surgery, LLC
Trade Name: Echelon Flex Powered Articulating Endoscopic Linear Cutters
Common Name: Cutter/Stapler
Product Code: GDW
Classification Name: Staple, Implantable; Stapler, Surgical
Regulation Number: 21 CFR 878.4750
Classification: Class II

FDA 510 (k) #: K130653 (K130653 is a modification to their original product cleared under K110385)

5. Description of the Device [21 CFR 807.92(a)(4)]

The Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads are sterile, single patient use instruments that simultaneously cut and staple tissue through a battery powered firing system. The Power Stapler and Reloads are sterilized by irradiation. The instruments deliver six staggered rows of staples, three on either side of the cut line.

The instruments are available in three shaft lengths: compact (192±20mm), regular (252±20mm) and long (352±20mm). The shaft can rotate freely in both directions and incorporates an articulation mechanism, which enables the distal portion of the shaft to pivot to facilitate lateral access to the operative site.

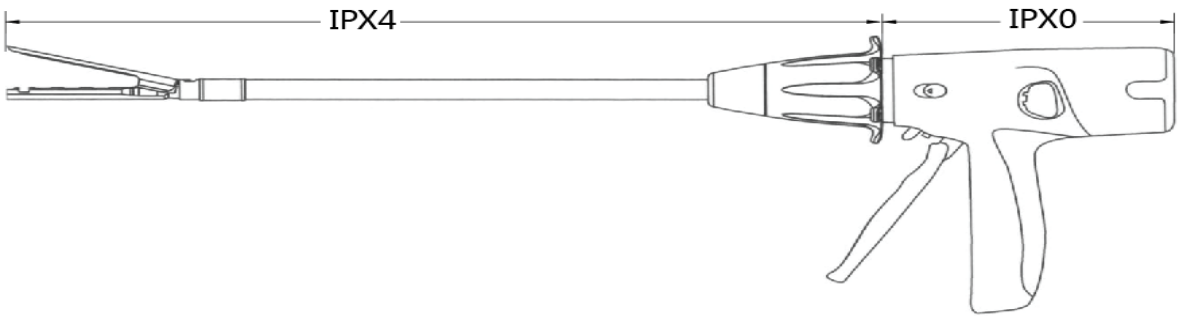
Model 30mm series include FSMS30，FSMM30，FSML30；45mm series include FSMS45，FSMM45，FSML45；60mm series include FSMS60，FSMM60，FSML60. The difference between the three series lies in the different anatomized lengths.

There are total 18 models of reloads within the proposed device, three stapler line length: 35.2±2.0mm，49.3±2.0mm and 61.3±2.0mm; six staple heights: Gray (0.75mm), White (1.0mm), Blue (1.5mm), Gold (1.8mm), Green (2.0mm), Black (2.3mm).

Power type: internal power supply; DC voltage 12V, rated power 40W
Applied parts：Type CF
Mode of operation：Non-Continuous Operation

Degree of safety when used in the presence of flammable anesthetic gas mixed with flammable anesthetic gas or nitrous oxide mixed with air: Flammable anesthetic gas that cannot be mixed with flammable anesthetic gas or nitrous oxide mixed with air .

The Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads is resistant to water ingress. Grade of waterproof：Rotating knob to the end of tubular shaft (including rotating knob) is rated IPX4; the Body is rated IPX0.



6. Indications For Use [21 CFR 807.92(a)(5)]

The Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general abdominal, gynecologic, thoracic, and pediatric surgical procedures.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

The technological characteristics are the same or very similar to the predicate device.

Surgical stapling is the technological principle for both the subject and predicate device. It is based on the use of endoscopic instrumentation for transection, resection, and/or creation of anastomoses.

The subject and predicate staplers and reloads share the following features:

- Intended Use
- Technological characteristics
- Operational principles
- Sterilization Method

8. Non-Clinical and Clinical Tests

The device passed the following tests.

Non-Clinical Test	Appearance
	Flexibility
	Assembling capacity
	Hardness
	Anastomosis and cutting performance
	Resistance to Pressure

	Safety Device
	Sharpness
	Surface Roughness
	Package Seal
	Rotation and Articulation
	Firing Electric Current
	Battery Voltage
	Motor Rotate Speed
	Size
	Sterility Test
	Accelerated Aging Test (ASTM F1980-16)
	Seal Strength Test (ASTM F 88/F-15)
	Dye Penetration Test (ASTM F1929-15, ASTM F3039-15)
	Vacuum Leak Test(ASTM D3078-2002(2013))
	Packaging Resistance Bacteria Performance Test(DIN 58953-6-2010)
Biocompatibility Test	In Vitro Cytotoxicity Test（ISO 10993-5: 2009 ）
	Skin Sensitization Test（ISO 10993-10:2010）
	Intracutaneous reactivity Test（ISO 10993-10:2010）
	Acute Systemic Toxicity（ISO 10993-11:2006）
	Pyrogen Test（ISO 10993-11:2006）
	Subchronic Systemic Toxicity（ISO 10993-11:2006）
	Ames test（ISO 10993-3: 2014）
	In vitro Mammalian Chromosome Aberration Test（ISO 10993-3:2014）
	In Vivo Mammalian Erythrocyte Micronucleus Test（ISO 10993-3:2014 ）
	Muscle Implantation Test（ISO 10993-6: 2016 ）
Electrical Safety Test	Electrical Safety Test（AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012,c1:2009/(r)2012 and a2:2010/(r)2012）
EMC Test	EMC Test (IEC60601-1-2:2014)

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Product Name	Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads	Echelon Flex Powered Articulating Endoscopic Linear Cutters (K130653) K130653 is a modification to their original product cleared under K110385
Classification	II	II
Regulation Number	21 CFR 878.4750	21 CFR 878.4750
Product Code	GDW	GDW
Intended Use	The Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general abdominal, gynecologic, thoracic, and pediatric surgical procedures.	The Echelon families of endoscopic linear cutters (articulating and straight) are intended for transection, resection, and/or creation of anastomoses. The instruments have application in multiple open or minimally invasive general, gynecologic, urologic, thoracic, and pediatric surgical procedures. They can be used with staple line or tissue buttressing materials. The instruments may also be used for transection and resection of liver parenchyma (hepatic vasculature and biliary structures), pancreas, kidney and spleen.
Cutting Mechanism	Stapler places two, triple staggered rows of staples and simultaneously cuts and divides the tissue between the two row.	Stapler places two, triple staggered rows of staples and simultaneously cuts and divides the tissue between the two row.
Manual/Powered	Powered	Powered
Safety Feature	Power stapler has empty-reload safety protection mechanism.	Power stapler has empty-reload safety protection mechanism.
Main Components	Closing Trigger, Red Firing Trigger Lock, Firing Trigger, Anvil Release Button, Battery Pack, Battery Pack Release Tab, Manual Override	Closing Trigger, Red Firing Trigger Lock, Firing Trigger, Anvil Release Button, Battery Pack, Battery Pack Release Tab, Manual Override

<table>
<tr><td></td><td>Access Panel, Knife Reverse Switch, Rotating Knob, Articulation Fins, Reload(Cartridge), Reload Gripping Surface, Reload Alignment Tab, Reload Alignment Slot, Staple Retaining Cap, Anvil Jaw, Cartridge Jaw, Staple Line, Cut Line, Proximal Black Line , Knife Blade Indicator, Indicator</td><td>Access Panel, Knife Reverse Switch, Rotating Knob, Articulation Fins, Reload(Cartridge), Reload Gripping Surface, Reload Alignment Tab, Reload Alignment Slot, Staple Retaining Cap, Anvil Jaw, Cartridge Jaw, Staple Line, Cut Line, Proximal Black Line , Knife Blade Indicator</td></tr>
<tr><td rowspan="3">Staple Line Length</td><td>30mm</td><td>N/A</td></tr>
<tr><td>45mm</td><td>45mm</td></tr>
<tr><td>60mm</td><td>60mm</td></tr>
<tr><td>Open Staple Height</td><td>2.0mm, 2.5mm, 3.5mm, 3.8mm, 4.1mm, 4.4mm</td><td>No Known</td></tr>
<tr><td>Open Staple Picture</td><td>  </td><td>  </td></tr>
<tr><td rowspan="6">Closed Staple Height</td><td>0.75mm</td><td>0.75mm</td></tr>
<tr><td>1.0mm</td><td>1.0mm</td></tr>
<tr><td>1.5mm</td><td>1.5mm</td></tr>
<tr><td>1.8mm</td><td>1.8mm</td></tr>
<tr><td>2.0mm</td><td>2.0mm</td></tr>
<tr><td>2.3mm</td><td>2.3mm</td></tr>
<tr><td>Closed Staple Picture</td><td>  </td><td>  </td></tr>
<tr><td rowspan="3">Number of Staples</td><td>36</td><td>N/A</td></tr>
<tr><td>70</td><td>70</td></tr>
<tr><td>88</td><td>88</td></tr>
<tr><td>Staple Cross Section</td><td>0.03 mm^2</td><td>No Known</td></tr>
<tr><td>Patient-Contact Material</td><td><table><tr><td>Contact Component</td><td>Material</td></tr></table></td><td>No Known</td></tr>
</table>

	Anvil	SUS420(Stainless 20Cr13) SUS630(Stainless 05Cr17Ni4Cu4Nb/0Cr17Ni4Cu4Nb)	
	Reload seat	SUS630(Stainless 05Cr17Ni4Cu4Nb/0Cr17Ni4Cu4Nb)	
	Cutting knife	SUS440(Stainless 85Cr17)	
	Aluminum ring	2A12-T4	
	Left Pipe	SUS304(Stainless 06Cr19Ni10)	
	Right Pipe	SUS304 (Stainless 06Cr19Ni10)	
	Reload	LCP, PC	
	Pushing plate	RTP4007A	
	Bracket	SUS304(Stainless 06Cr19Ni10)	
	Cover	PU	
	Staple	Ti-3AL-2.5V(TA18)	
Sterilization	Sterilized by Irradiation		Sterilized by Irradiation
SAL	10^{-6}		Not Known, but assumed to be 10^{-6}

10. Conclusion [21 CFR 807.92(b)(3)]

The Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads device is substantially equivalent to the predicate device because both devices use the same or similar technology and have the same intended use. Testing to relevant standards demonstrate the device will perform as intended. The differences between the devices are insignificant and do not raise different questions of safety and effectiveness for the Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads device.