December 14, 2020

Fengh Medical Co., Ltd.
℅ Julie Chen
Technical Manager
Shanghai Medical Business Consulting Co., Ltd.
No. 170 Huajiang Road, Jiading District
Shanghai, 201801 Cn

Re: K202467
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 23, 2020
Received: December 2, 2020

Dear Julie Chen:

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.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202467

Device Name

Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads

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)]

July 20th, 2020

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

Company Name: Fengh Medical Co., Ltd.
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Submission Correspondent： Julie Chen
Email: julie.chen@mind-link.net
Tel: +86 139 1804 5781

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

Trade Name: Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads **Stapler models include** FSAS30, FSAS45, FSAS60, FSAM30, FSAM45, FSAM60, FSAL30, FSAL45, FSAL60, FNMS30, FNMS45, FNMS60, FNMM30, FNMM45, FNMM60, FNML30, FNML45, FNML60, FNAS30, FNAS45, FNAS60, FNAM30, FNAM45, FNAM60, FNAL30, FNAL45, FNAL60, DSMS30, DSMS45, DSMS60, DSMM30, DSMM45, DSMM60, DSML30, DSML45, DSML60, DSAS30, DSAS45, DSAS60, DSAM30, DSAM45, DSAM60, DSAL30, DSAL45, DSAL60, DNMS30, DNMS45, DNMS60, DNMM30, DNMM45, DNMM60, DNML30, DNML45, DNML60, DNAS30, DNAS45, DNAS60, DNAM30, DNAM45, DNAM60, DNAL30, DNAL45, DNAL60, **Reloads models include** FACC30, FACC45, FACC60, FACW30, FACW45, FACW60, FACB30, FACB45, FACB60, FACG30, FACG45, FACG60, FACY30, FACY45, FACY60, FACX30,

	FACX45, FACX60, DMCC30, DMCC45, DMCC60, DMCW30, DMCW45, DMCW60, DMCB30, DMCB45, DMCB60, DMCG30, DMCG45, DMCG60, DMCY30, DMCY45, DMCY60, DMCX30, DMCX45, DMCX60, DACC30, DACC45, DACC60, DACW30, DACW45, DACW60, DACB30, DACB45, DACB60, DACG30, DACG45, DACG60, DACY30, DACY45, DACY60, DACX30, DACX45, DACX60
Common Name:	Implantable staple
Product Code:	GDW
Regulation Number:	21 CFR 878.4750
Device Class:	II

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

The identification of predicates within this submission is as follow:

Manufacturer:	Fengh Medical Co., Ltd.
Trade Name:	Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads, **Stapler models include** FSMS30, FSMM30, FSML30, FSMS45, FSMM45,FSML45, FSMS60, FSMM60, FSML60 **Reloads models include** FMCC30, FMCW30, FMCB30, FMCG30, FMCY30, FMCX30, FMCC45, FMCW45, FMCB45, FMCG45, FMCY45, FMCX45, FMCC60, FMCW60, FMCB60, FMCG60, FMCY60, FMCX60
FDA 510 (k) #:	K182476
Common Name:	Cutter/Stapler
Product Code:	GDW
Classification Name:	Staple, Implantable; Stapler, Surgical
Regulation Number:	21 CFR 878.4750
Classification:	Class II

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.

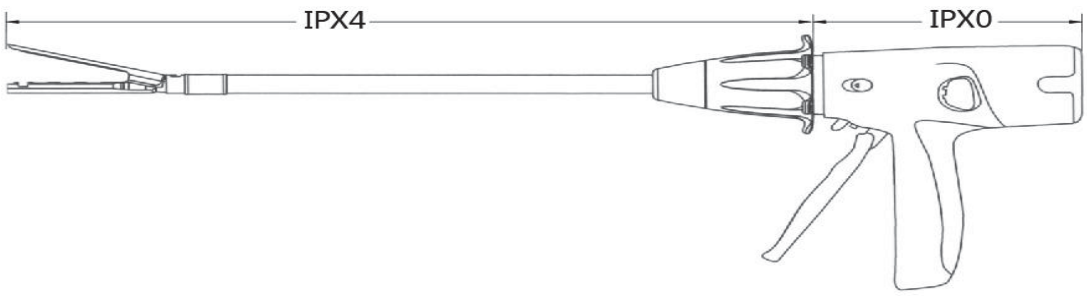
Model 30mm series include FSAS30, FSAM30, FSAL30, FNMS30, FNMM30, FNML30, FNAS30, FNAM30, FNAL30, DSMS30, DSMM30, DSML30, DSAS30, DSAM30, DSAL30, DNMS30, DNMM30, DNML30, DNAS30, DNAM30, DNAL30; Model 45mm series include FSAS45, FSAM45, FSAL45, FNMS45, FNMM45, FNML45, FNAS45, FNAM45, FNAL45, DSMS45, DSMM45, DSML45, DSAS45, DSAM45, DSAL45, DNMS45, DNMM45, DNML45, DNAS45, DNAM45, DNAL45； Model 60mm series include FSAS60, FSAM60, FSAL60, FNMS60, FNMM60, FNML60, FNAS60, FNAM60, FNAL60, DSMS60, DSMM60, DSML60, DSAS60, DSAM60, DSAL60, DNMS60, DNMM60, DNML60, DNAS60, DNAM60, DNAL60. The difference between the three series lies in the different anatomized lengths. FSA/DSM/DSA series exclude reloads remover, and FNA/DNM/DNA/ FNM series include reloads remover.

There are total 54 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); three colors of cap. FAC series is purple, DAC series is yellow, and DMC series is orange.

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

Device Characteristic	Proposed Device	Predicate Device (K182476)	SE Discussion
Product Name	Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads	Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads	N/A
Classification	II	II	Same
Regulation Number	21 CFR 878.4750	21 CFR 878.4750	Same
Product Code	GDW	GDW	Same
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 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.	Same

Manual/Powered	Powered	Powered	Same
Cutting Mechanism	Stapler places two, triple staggered rows of staples and simultaneously cuts and divides the tissue between the two rows.	Stapler places two, triple staggered rows of staples and simultaneously cuts and divides the tissue between the two rows.	Same
Safety Feature	Stapler have empty-reload safety protection mechanism.	Stapler have empty-reload safety protection mechanism.	Same
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	Same
Materials	Staples: titanium alloy Shaft: stainless steel Cover: polyurethane	Staples: titanium alloy Shaft: stainless steel Cover: polyurethane	Same
Staple Shape	Standard “B” shaped staple	Standard “B” shaped staple	Same
Staple Height (closed)	0.75mm,1.0mm,1.5mm,1.8mm 2.0mm, 2.3mm	0.75mm,1.0mm,1.5mm,1.8mm 2.0mm, 2.3mm	Same
Staple Line Length	30mm,45mm,60mm	30mm,45mm,60mm	Same
Sterilization	Sterilized by Irradiation	Sterilized by Irradiation	Same
Biocompatibility	Reloads are biocompatible	Reloads are biocompatible	Same
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)	Electrical Safety Test (AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012)	Same
EMC Test	EMC Test (IEC60601-1-2:2014)	EMC Test (IEC60601-1-2:2014)	Same

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

The Disposable Powered Articulating Endoscopic Linear Cutter Stapler has not changed in the basic design, mechanism of action, intended use when compared to the predicate device. There is no change to reloads in material and structure. The only difference in the current submitted device is the physical appearance of rotating knob, shells and addition of reloads removers.

9. Performance Data

Non-Clinical Performance Test Conclusion

There is no FDA recognized performance standard for implanted reloads and staplers. Non-clinical tests were conducted to verify that the proposed device met the requirements of design change and was Substantially Equivalent (SE) to the predicate device. The testing was as follows:

- Visual Appearance
- Sterility
- Package Seal
- Hardness
- Anastomosis and Cutting Performance
- Safety Device
- Pressure Resistant Properties
- Sharpness
- Surface Roughness
- Flexibility
- Matching Performance
- Firing Electric Current
- Battery Voltage
- Motor Rotation Speed
- Dimensions

During verification testing, all data meets pre-defined criteria.

Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device, Disposable Powered Articulating Endoscopic Linear Cutter Stapler & Reloads is substantially equivalent to the predicate device.