February 12, 2018

Teleflex Medical, Inc.
Holly Hallock
Regulatory Affairs Manager
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K172775
Trade/Device Name: Teleflex MiniLap System with ThumbGrip Handle,
Teleflex MiniLap System with ThumbGrip MiniPolar Handle,
Teleflex MiniLap System with MiniGrip Handle,
Teleflex MiniLap System with MiniGrip BiPolar Handle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OCW, GEI
Dated: September 12, 2017
Received: September 14, 2017

Dear Holly Hallock:

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 below.

510(k) Number *(if known)*

K172775

Device Name
Teleflex MiniLap® System with ThumbGrip Handle

Indications for Use *(Describe)*
MiniLap instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold, and manipulate other soft internal tissues, as well as items such as hernia mesh, during pediatric and adult surgery.

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.

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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 below.

510(k) Number *(if known)*

Device Name
Teleflex MiniLap® System with ThumbGrip MiniPolar® Handle

Indications for Use *(Describe)*
The MiniPolar Instruments are used to cut and cauterize soft tissue during pediatric and adult surgery.

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)

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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 below.

510(k) Number *(if known)*

Device Name
Teleflex MiniLap® System with MiniGrip® Handle

Indications for Use *(Describe)*
The MiniLap System with MiniGrip Handles grasping instruments have applications in a variety of general, thoracic, gynecologic, urologic, laparoscopic and endoscopic procedures for manipulation of tissue, as well as items such as hernia mesh, during pediatric and adult surgery.

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)

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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 below.

510(k) Number *(if known)*

Device Name
Teleflex MiniLap® System with MiniGrip® BiPolar Handle

Indications for Use *(Describe)*
Bipolar Grasper instruments with bipolar cautery have applications in a variety of general, thoracic, gynecologic (except for use in female sterilization), urologic, laparoscopic, and endoscopic procedures for manipulation and coagulation of tissue and for manipulation of items such as hernia mesh during pediatric and adult surgery.

The male bipolar connection is located at the back of the handle and may be utilized for bipolar applications when attached to standard two plug bipolar cables and their generators (a male connection is provided as an integral part of the instrument).

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

MiniLap® Percutaneous Surgical System: ThumbGrip Instruments and MiniGrip® Graspers

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560

Phone: 919-433-4918
Fax: 919-433-4996

B. Contact Person

Holly Hallock
Regulatory Affairs Manager

C. Date Prepared

February 9, 2018

D. Device Name

Trade Name	Teleflex MiniLap® System with ThumbGrip Handle
Common Name	Endoscopic Tissue Approximation Device
Classification Name	Endoscopic and accessories
Trade Name	Teleflex MiniLap® System with ThumbGrip MiniPolar® Handle
Common Name	Electrosurgical, Cutting & Coagulation & Accessories
Classification Name	Electrosurgical cutting and coagulation device and accessories
Trade Name	Teleflex MiniLap® System with MiniGrip® Handle
Common Name	Endoscopic Tissue Approximation Device
Classification Name	Endoscopic and accessories

Trade Name	Teleflex MiniLap® System with MiniGrip® BiPolar Handle
Common Name	Electrosurgical, Cutting & Coagulation & Accessories
Classification Name	Electrosurgical cutting and coagulation device and accessories

E. Device Description

The Teleflex MiniLap® Percutaneous Surgical System is a family of minimally invasive surgical devices that provide a surgeon with the means to penetrate soft tissue to access certain areas of the human anatomy, then grasp, hold and manipulate other soft internal tissue within the body that are related to the surgical procedure.

Please note that this is a bundled submission; the MiniLap Percutaneous Surgical System has two families presented in this 510(k). The first is the MiniLap ThumbGrip Instruments, which have a thumb grip handle to control the instrument tips. These instruments are available in electrosurgical and non-electrosurgical configurations. The second product family discussed in this 510(k) is the MiniLap MiniGrip Graspers, which have a pistol grip handle that allows single handed device operation to control the jaws. While these graspers are currently only cleared for electrosurgical configurations (K113597), the intent of this 510(k) is to support non-electrosurgical configurations of the MiniGrip Graspers as well.

ThumbGrip Instruments and MiniGrip Graspers are disposable manual instruments designed for direct introduction to the surgical site without the need for a traditional insertion conduit. These instruments are used for grasping, holding and manipulating soft internal tissues. These percutaneous instruments provide the benefit of reduced trauma due to no surgical incision closure and the elimination of one or more trocars.

ThumbGrip Instruments
MiniLap ThumbGrip Instruments consist of an integrated needle/cannula shaft that houses a retractable working instrument. The shaft can be introduced percutaneously to the surgical site, after which the working instrument can be deployed for grasping and manipulating or cauterizing tissue. The ThumbGrip Instruments are available in electrosurgical and non-electrosurgical configurations, with shaft diameters of 2.4mm and 2.3mm, respectively. A stabilizing pivot disk is available on the non-electrosurgical configurations that can be stuck to the skin of the patient to provide entry-depth control, and a banana plug is available on the electrosurgical configurations for monopolar energy. The working instrument is controlled through the thumb handle and a locking mechanism on the proximal end of the device.

ThumbGrip Instruments		
Model Number	**Name**	**Configuration**
GBC250	ThumbGrip Alligator Grasper	Non-electrosurgical
CLC250	ThumbGrip Clutch Grasper	

BCK250	ThumbGrip Babcock Grasper	
BLC250	ThumbGrip Bowel Grasper	
GBC200	ThumbGrip Alligator Grasper Short	
ECMC300	ThumbGrip Curved Spatula Probe	Electrosurgical with monopolar energy (“MiniPolar”)
ECMS300	ThumbGrip Straight Spatula Probe	
ECMH300	ThumbGrip Hook Probe	
ECMP300	ThumbGrip Conical Probe	

MiniGrip Graspers

The MiniLap MiniGrip Graspers consist of an integrated 2.4mm needle/cannula shaft that houses a retractable grasper. The shaft, which is insulated for electrosurgical configurations, can be introduced percutaneously to the surgical site, after which the working portion of the instrument can be deployed to approximate and grasp soft tissue.

The grasper jaws are controlled by a pistol-grip handle. The orientation of the jaws relative to the handle can be adjusted by the rotation hub. The ratchet function of the handle locks the position of the jaws in a closed or free mode. The “ON” position locks the jaws together for insertion and removal of the jaws. The “OFF” position of the ratchet allows for free motion of the jaws. The arming button allows the surgeon to arm the device (insertion needle out). A red indication will be visible under the arming button when the needle is exposed.

MiniGrip Graspers		
Model Number	**Name**	**Configuration**
BPS300	MiniGrip BiPolar Grasper	Electrosurgical with bipolar energy
PGAC300	MiniGrip Alligator Grasper	Non-electrosurgical
PGCC300	MiniGrip Clutch Grasper	
PGBK300	MiniGrip Babcock Grasper	
PGBC300	MiniGrip Tong Grasper	
PGAC200	MiniGrip Alligator Grasper Short	

The ThumbGrip MiniPolar Instruments connect to most electrosurgical units (ESUs) via a standard monopolar cable, as they provide monopolar energy. The MiniGrip BiPolar Graspers connect to most ESUs via a standard bipolar cable, as they provide bipolar energy. An example of an ESU that may be used with both of these products families is Valleylab Force FX.

F. Indications for Use and Contraindications

ThumbGrip Instruments

Indications:

MiniLap instruments are a family of minimally invasive devices with the means to penetrate soft tissue to access certain areas of the human anatomy. The devices are used to grasp, hold, and manipulate other soft internal tissues, as well as items such as hernia mesh, during pediatric and adult surgery.

Contraindications:
The device is not for use when laparoscopic techniques generally are contradicted.

ThumbGrip MiniPolar Instruments

Indications:
The MiniPolar Instruments are used to cut and cauterize soft tissue during pediatric and adult surgery.

Contraindications:
The device is not intended for use when endoscopic techniques are generally contraindicated.

Do not resterilize. The device is provided sterile and is intended for use in a single procedure. Discard after use.

The MiniPolar instruments with monopolar cautery are not intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.

MiniGrip Graspers

Indications:
The MiniLap System with MiniGrip Handles grasping instruments have applications in a variety of general, thoracic, gynecologic, urologic, laparoscopic and endoscopic procedures for manipulation of tissue, as well as items such as hernia mesh, during pediatric and adult surgery.

Contraindications:
Blind insertion in laparoscopic surgery.

The device is provided STERILE and it is intended for use in a SINGLE procedure, DISCARD AFTER USE. DO NOT RE-STERILIZE.

MiniGrip BiPolar Graspers

Indications:
Bipolar Grasper instruments with bipolar cautery have applications in a variety of general, thoracic, gynecologic (except for use in female sterilization), urologic, laparoscopic, and endoscopic procedures for manipulation and coagulation of tissue and for manipulation of items such as hernia mesh during pediatric and adult surgery.

The male bipolar connection is located at the back of the handle and may be utilized for bipolar applications when attached to standard two plug bipolar cables and their generators (a male connection is provided as an integral part of the instrument).

Contraindications:
The device is not intended for use when endoscopic techniques are generally contraindicated.

Blind insertion in laparoscopic surgery.

The device is provided STERILE and is intended for use in a SINGLE procedure, DISCARD AFTER USE. DO NOT RESTERILIZE.

This device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures.

G. Substantial Equivalence

The proposed MiniLap ThumbGrip Instruments (non-electrosurgical) are substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
MINI LAP Instruments	Teleflex	K070686	April 05, 2007
MINI LAP Pediatric Instruments with Medusa Clamping System	Mini-Lap Technologies	K070352	April 05, 2007

The proposed MiniLap ThumbGrip MiniPolar Instruments are substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
MINI LAP Electrocautery Instruments	Teleflex	K083754	November 30, 2009
MINI LAP Pediatric Instruments with Medusa Clamping System	Mini-Lap Technologies	K070352	April 05, 2007

The proposed MiniLap MiniGrip Graspers (non-electrosurgical) are substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
MINI-LAP BIPOLAR ELECTROCAUTERY DEVICES	Mini-Lap Technologies	K113597	June 03, 2012
MINI LAP Pediatric Instruments with Medusa Clamping System	Mini-Lap Technologies	K070352	April 05, 2007

The proposed MiniLap MiniGrip BiPolar Graspers are substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
MINI-LAP BIPOLAR ELECTROCAUTERY DEVICES	Mini-Lap Technologies	K113597	June 03, 2012
MINI LAP Pediatric Instruments with Medusa Clamping System	Mini-Lap Technologies	K070352	April 05, 2007

H. Comparison To Predicate Devices

The proposed MiniLap Percutaneous Surgical System, including the ThumbGrip Instruments and MiniGrip Graspers, has the same technology and functional characteristics as the predicate devices.

Additionally, the devices included in this submission have been on the market for several years with no substantial modifications. The manufacturer of the devices included in this submission is the same manufacturer of the predicate devices referenced. (Note: Teleflex Medical previously acquired the assets of Mini-Lap Technologies.)

I. Materials

The proposed MiniLap Percutaneous Surgical System, including the ThumbGrip Instruments and MiniGrip Graspers, has the same patient contacting materials as the predicate devices. All materials are in compliance with ISO 10993-1.

J. Technological Characteristics

A comparison of the technological characteristics of the proposed MiniLap Percutaneous Surgical System, including the ThumbGrip Instruments and MiniGrip Graspers and their predicate devices, has been performed. The results of this comparison demonstrate that the ThumbGrip Instruments and MiniGrip Graspers are equivalent to the marketed predicate devices in technological and performance characteristics.

K. Performance Data

Ship testing, which has been performed in accordance with ISO 11607-1 *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*, demonstrates that the ThumbGrip Instruments and MiniGrip Graspers are substantially equivalent to their predicate devices.

Additionally, design verification and validation of the ThumbGrip Instruments and MiniGrip Graspers was conducted to document that the device performed to the intended use. All verification and validation results support substantial equivalence.

Electrosurgical devices have been tested to IEC 60601-1 *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance*.

Please note that the predicate devices previously all had shelf lives of 2 years. However, recent stability testing supported extending the shelf life of the MiniGrip Graspers (non-electrosurgical) and the ThumbGrip Instruments (electrosurgical) from 2 years to 5 years.

L. Conclusion

Based upon the discussions above comparing the materials, the technological characteristics, and the performance data, the proposed MiniLap Percutaneous Surgical System, including the ThumbGrip Instruments and MiniGrip Graspers, is substantially equivalent to the predicate devices cleared to market via 510(k)s K070352, K070686, K083754, and K113597.