October 12, 2018

Teleflex Medical, Inc.
Kim Campbell
Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K181852
Trade/Device Name: Percuvance Percutaneous Surgical System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, GCJ, GDO
Dated: September 19, 2018
Received: September 21, 2018

Dear Kim Campbell:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

FDA

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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)*

K181852

Device Name
Percuvance(TM) Percutaneous Surgical System

Indications for Use *(Describe)*
The Percutaneous Surgical System with 5mm attachments is indicated for the means to penetrate soft tissue to access certain areas of the abdomen. The system is used to grasp, manipulate, cut, cauterize and deliver Hem-o-lok® ligating clips to soft tissue during laparoscopic 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.

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510(k) SUMMARY

Percuvance™ Percutaneous Surgical System

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

Teleflex Medical, Incorporated
3015 Carrington Mill Boulevard
Morrisville, NC 27560 USA
Phone:919-433-4918
Fax: 919-433-4996

B. Contact Person

Kim Campbell
Regulatory Affairs Specialist

C. Date Prepared

September 19th, 2018

D. Device Name

Trade Name

Percuvance™ Percutaneous Surgical System

Common Name

Primary:	Electrosurgical, Cutting and Coagulation and Accessories
Secondary:	Laparoscope, General and Plastic Surgery Applier, Surgical, Clip

Classification Regulation

Primary:	21 CFR 878.4400
Secondary:	21 CFR 876.1500 21 CFR 878.4800

Product Code

Primary:	GEI
Secondary:	GCJ, GDO

Classification Name

Primary: Electrosurgical Cutting and Coagulation Device and Accessories

Secondary: Endoscope and Accessories
Manual Surgical Instrument for General Use

Classification

Class II

Panel

General & Plastic Surgery

E. Device Description

Teleflex Medical's Percuvance™ Percutaneous Surgical System is a micro-laparoscopic platform that comprises fourteen (14) unique components, which are combined in various configurations to create a multifunctional set of instruments for laparoscopic procedures. In accordance with IEC 60601-1:2005 (A1:2012), the Percuvance™ system is classified as a BF active accessory with a rated accessory voltage of $1000V_{Peak}$.

System components include two reusable Handles (Ratcheted and Non-Ratcheted), which are manipulated by the surgeon and connect to a Shaft. The Shaft, which is available in two lengths (29 cm and 36 cm), affords various Tool Tips (or End Effectors) to be attached in order to perform basic surgical manipulations. The Percuvance™ Handles, Shafts, and Tool Tips are not compatible or interchangeable with components from other percutaneous systems.

Initial access to the surgical site is achieved with the Introducer Tool Tip attached to the Shaft. Once inside the patient, the Introducer Tool Tip is extracorporealized through a pre-inserted, central trocar and is then exchanged for one of the other Tool Tips, which include Scissors, Gripper Grasper, Johans Grasper, Maryland Dissector, Hook Cautery, Spatula Cautery and Clip Applier. No ligating clips are provided with the Percuvance™ Percutaneous Surgical System; however, the Clip Applier Tool Tip is compatible with Teleflex Medical's M/L Hem-o-lok® ligating clip (SKU 544230).

Finally, the Seal Bridge, which is available in two sizes (5 mm and 12 mm), is used to protect the trocar seal and to aid in maintaining insufflation when it used in conjunction with a trocar to facilitate the extracorporeal exchange of Tool Tips.

Model Number	Component Description	Reusability Status	Sterility Status	Intended to Apply Monopolar Energy?
PCVINT3	Introducer Tool Tip	Single-Patient-Use	Provided Sterile – Gamma Irradiated	No
PCVSC5	Scissors Tool Tip	Single-Patient-Use	Provided Sterile – Gamma Irradiated	Yes

Model Number	Component Description	Reusability Status	Sterility Status	Intended to Apply Monopolar Energy?
PCVGG5	Traumatic Gripper Grasper Tool Tip	Single-Patient-Use	Provided Sterile – Gamma Irradiated	Yes
PCVJG5	Atraumatic Johans Grasper Tool Tip	Single-Patient-Use	Provided Sterile – Gamma Irradiated	Yes
PCVMD5	Maryland Dissector Tool Tip	Single-Patient-Use	Provided Sterile – Gamma Irradiated	Yes
PCVHK5	Hook Cautery Tool Tip	Single-Patient-Use	Provided Sterile – Gamma Irradiated	Yes
PCVSPT5	Spatula Cautery Tool Tip	Single-Patient-Use	Provided Sterile – Gamma Irradiated	Yes
PCVHCA5	Clip Applier Tool Tip	Single-Patient-Use	Provided Sterile – Gamma Irradiated	No
PCVSH3	29 cm Shaft	Single-Patient-Use	Provided Sterile – Gamma Irradiated	Yes
PCVSHL3	36 cm Shaft	Single-Patient-Use	Provided Sterile – Gamma Irradiated	Yes
PCVNRH	Non-Ratcheted Handle	Reusable	Provided Non-Sterile – Intended to be Steam Sterilized by Hospital	Yes
PCVRH	Ratcheted Handle	Reusable	Provided Non-Sterile – Intended to be Steam Sterilized by Hospital	Yes
PCVSB5	5 mm Seal Bridge	Single-Patient-Use	Provided Sterile – Gamma Irradiated	N/A – Not connected to the Handle and Shaft configuration
PCVSB12	12 mm Seal Bridge	Single-Patient-Use	Provided Sterile – Gamma Irradiated	N/A – Not connected to the Handle and Shaft configuration

F. Indications for Use

The Percutaneous Surgical System with 5mm attachments is indicated for the means to penetrate soft tissue to access certain areas of the abdomen. The system is used to grasp, manipulate, cut, cauterize and deliver Hem-o-lok® ligating clips to soft tissue during laparoscopic surgery.

G. Contraindications

The following are contraindications of the Percuvance™ Percutaneous Surgical System:

- The monopolar active Tool Tips are not intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube.

- Do not resterilize single patient use components. These components are provided sterile and are intended for use in a single procedure. Discard after use.

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

The following are contraindications of the M/L Hem-o-lok® ligating clip (SKU 544230), which is an accessory to the Percuvance™ system:

- Hem-o-lok® ligating clips are not intended for use as a fallopian contraceptive tubal occlusion device.

- Hem-o-lok® ligating clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies.

H. Substantial Equivalence

The Percuvance™ Percutaneous Surgical System is substantially equivalent to the following predicate system.

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Percuvance™ Percutaneous Surgical System	Teleflex Medical, Inc.	K153063	April 8th, 2016

Additionally, the technology of Teleflex Medical's Percuvance™ Clip Applier Tool Tip is substantially equivalent to that of the M/L Hem-o-lok® manual, endoscopic clip appliers cleared in 510(k) K133202. Like the M/L Hem-o-lok® manual, endoscopic clip appliers, the Percuvance™ Clip Applier Tool Tip is compatible with Teleflex Medical's M/L Hem-o-lok® ligating clip (SKU 544230), which was also cleared in 510(k) K133202.

Reference (Accessory) Device	Manufacturer	510(k) No.	Date Cleared
Hem-o-lok® Ligating Clip System	Teleflex Medical, Inc.	K133202	December 3, 2013

I. Comparison to Predicate Device

The proposed Percuvance™ Percutaneous Surgical System is substantially equivalent to the predicate system with respect to technology, intended use, indications for use and functional characteristics. The proposed modifications to Percuvance™ Percutaneous System does not introduce any new issues of safety and effectiveness.

J. Materials

All patient contacting materials are equivalent to the predicate Percuvance™ Percutaneous Surgical System and have been evaluated in accordance with ISO 10993-1:2009 (C2010) and FDA Guidance: Use of International Standard ISO 10993 (published June 16, 2016), according to their nature and duration of contact.

K. Technological Characteristics

A comparison of the technological characteristics of the proposed Percuvance™ Percutaneous Surgical System and the predicate system has been performed. The results of this comparison demonstrate that the proposed system utilizes substantially equivalent technology as the predicate system.

Comparative Characteristics	**Predicate Device (K153063)** **Percuvance™ Percutaneous Surgical System**	**Proposed Device** **Percuvance™ Percutaneous Surgical System**
Indications for Use	The Percutaneous Surgical System with 5mm attachments is indicated for the means to penetrate soft tissue to access certain areas of the abdomen. The system is used to grasp, manipulate, cut, cauterize and deliver Hem-o-lok® ligating clips to soft tissue during laparoscopic surgery.	Equivalent
Intended Use	The Percutaneous Surgical System is a platform consisting of a percutaneous surgical set and accessories used as a means to penetrate soft tissue to access certain areas of the abdomen. The devices' Tool Tips or attachments are provided separately from the percutaneous Shaft and are introduced to the site via a traditional conduit such as a trocar once they are attached extracorporeally to the Shaft tip. A Seal Bridge is used in conjunction with the trocar to maintain insufflation during extracorporeally exchange. Once inside the abdomen, the surgical set is used to grasp, manipulate, cut, cauterize, and deliver Hem-o-lok® ligating clips to soft tissues during laparoscopic surgery.	Equivalent
Contraindications	The monopolar active Tool Tips are not intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transection of the fallopian tube. *(system contraindication)* Do not resterilize single patient use components. These components are provided sterile and are intended for use in a single procedure. Discard after use. *(system contraindication)* The device is not intended for use when endoscopic techniques are generally contraindicated. *(system contraindication)*	Equivalent

Comparative Characteristics	Predicate Device (K153063) Percuvance™ Percutaneous Surgical System	Proposed Device Percuvance™ Percutaneous Surgical System
	Hem-o-lok® ligating clips are not intended for use as a fallopian contraceptive tubal occlusion device. *(accessory ligating clip contraindication)* Hem-o-lok® ligating clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomies. *(accessory ligating clip contraindication)*	
Intended Procedure	Laparoscopic	Equivalent
Reusability Status	Handles are reusable; All other components are single patient use and disposable	Equivalent
Sterility Status	Handles are provided non-sterile and are intended to be sterilized by end user prior to use; All other components are provided sterile	Equivalent
Sterilization Method	Non-sterile (reusable) components to be steam sterilized by end user; Sterile components sterilized by gamma irradiation using method VDmax	Equivalent
Energy	Monopolar	Equivalent
Rated Accessory Voltage	1000 V_{Peak}	Equivalent
Connector Type	Handle Post	Equivalent
Electrosurgical Testing	CB Scheme (in compliance with IEC 60601-1 series 2nd and 3.1 Editions)	Equivalent
Handle	Yes	Equivalent
Shaft	Yes (2.9 mm)	Equivalent
Introducer Tip	Yes	Equivalent
Tool Tips	Yes (5 mm)	Equivalent
Graspers	Yes	Equivalent
Maryland Dissectors	Yes	Equivalent
Scissors	Yes	Equivalent
Cautery Tips	Yes (Spatula and Hook)	Equivalent
Clip Applier	Yes	Equivalent
Seal Bridges	Yes	Equivalent
Exchange Technology	Exchanged extracorporeally	Equivalent

L. Performance Data

Comprehensive bench testing was completed on the modifications identified below to ensure the system performed equivalently (or better) to the predicate system. Existing design, usability validations and packaging (ship) testing, performed on the predicate device still adequately covers the proposed device. Stability testing was repeated on the sterile components and their packaging to support the legacy extended 3 year shelf life according to aging methods and test methods previously submitted in the predicate 510(k) in support of the initial 1 year shelf life. Though the majority of the electrosurgical safety testing submitted for the system is still valid, certain electrosurgical safety tests were repeated at a third party test house to support the Shaft metal lock tube change.

Biocompatibility data submitted for the Percuvance system still adequately represents the proposed system, as no new patient contacting materials were introduced. However, as a result of Shaft's green ink band modification, which is pad printed on the Shaft's proximal knob, a full biocompatibility panel was completed. Additionally, cytotoxicity testing was performed on the Shaft metal lock tube change. The additional biocompatibility and cytotoxicity tests were performed as a conservative measure, as both modifications impacted parts of the device that are not intended to have any patient contact.

M. Conclusion

Based upon the testing presented throughout the submission and in this 510(k) Summary, Teleflex Medical's Percuvance™ Percutaneous Surgical System is substantially equivalent in to the predicate device cleared to market via 510(k) K153063. The modifications to the proposed Percuvance™ Percutaneous Surgical System do not introduce any new issues of safety and effectiveness.