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

April 8, 2016

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

Re: K153063
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: March 4, 2016
Received: March 7, 2016

Dear Ms. 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.

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" (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.

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,

Jennifer R. Stevenson -A

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)*
K153063

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 – K153063

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

Holly Hallock
Senior Regulatory Affairs Specialist

C. Date Prepared

April 7th, 2016

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 next generation 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 to be performed in a hospital setting. In accordance with IEC 60601-1:2005 (A1:2012), this next generation Percuvance™ system is classified as an 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 manipulation. The next generation Percuvance™ Handles, Shafts, and Tool Tips are not compatible or interchangeable with components from other percutaneous systems, including those of the existing Percuvance™ Percutaneous Surgical System, which was cleared under 510(k) K143299.

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.

All model numbers and associated descriptions of components included in the next generation Percuvance™ Percutaneous Surgical System are identified below.

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
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 following are indications for use of the next generation Percuvance™ Percutaneous Surgical System:

> 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.

These indications for use were primarily generated from identical indications for use identified from the predicate Percuvance™ Percutaneous Surgical System (K143299):

> The Percutaneous Surgical System with 5mm attachments is indicated for the means to penetrate soft tissue to access certain areas of the human abdomen and used to grasp, hold and manipulate tissue during laparoscopic surgery.

The only differences in these indications for use statements are that the next generation Percuvance™ Percutaneous Surgical System introduces the abilities to "cut, cauterize" and "deliver Hem-o-lok® ligating clips," which were generated from the predicate MiniLap® MiniPolar Electrocautery Instruments and the reference Hem-o-lok® Ligating Clip System, respectively.

The following are indications for use of the predicate MiniLap® MiniPolar Electrocautery Instruments (K083754):

> The MiniPolar Instruments are used to cut and cauterize soft tissue.

The following are indications for use of the reference Hem-o-lok® Ligating Clip System:

> Weck Hem-o-lok® Endoscopic Ligating Clip Appliers are indicated for use as delivery devices for Hem-o-lok® Ligating Clips.

These additions to the next generation Percuvance™ Percutaneous Surgical System's indications for use are not critical, as they were generated from predicate and reference devices that have already been cleared by the FDA.

G. Contraindications

The following are contraindications of the next generation 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

Teleflex Medical's next generation Percuvance™ Percutaneous Surgical System is substantially equivalent to the following predicate systems.

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Percuvance™ Percutaneous Surgical System	Teleflex Medical, Inc.	K143299	January 21, 2015
MiniLap® MiniPolar Electrocautery Instruments	Teleflex Medical, Inc.	K083754	November 20, 2009

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 Devices

Teleflex Medical's next generation Percuvance™ Percutaneous Surgical System is substantially equivalent to the predicate systems with regards to technology, intended use, indications for use and functional characteristics.

One predicate system is Teleflex Medical's existing Percuvance™ Percutaneous Surgical System, which is legally marketed under 510(k) K143299. Like the next generation Percuvance™ system, the existing Percuvance™ system is a micro-laparoscopic system comprised of a multifunctional set of instruments that reduces the need for ports during laparoscopic procedures. Both systems are indicated for the penetration of soft tissue to access certain areas of the abdomen and used to grasp, hold and manipulate tissue.

Like this predicate system, the next generation Percuvance™ system utilizes an Introducer Tool Tip, Shaft and Handle to percutaneously introduce the system into the patient's surgical site. After introduction, both systems are capable of exchanging the Introducer Tool Tip for a variety of other Tool Tips in order to perform the surgical steps of the laparoscopic procedure. Each Percuvance™ system also includes a Seal Bridge, which is used to protect the trocar seal and to aid in maintaining insufflation when used in conjunction with a trocar to facilitate the extracorporeal exchange of Tool Tips.

The next generation Percuvance™ Percutaneous Surgical System combines the features of the existing Percuvance™ System with the electrosurgical features of Teleflex Medical's MiniLap® MiniPolar Electrocautery Instruments, which are legally marketed under 510(k) K083754. The MiniLap® system, which is also a predicate device, is a percutaneous system that allows surgeons to apply RF energy through a variety of monopolar instruments. Like the predicate MiniLap® system, the next generation Percuvance™ system includes a Hook Cautery Tool Tip and a Spatula Cautery Tool Tip for the application of monopolar RF energy.

A manual Clip Applier Tool Tip has also been added to the next generation Percuvance™ system to afford users the ability to ligate. While ligation clips are not provided with the next generation Percuvance™ system, the manual Clip Applier Tool Tip is compatible with M/L Hem-o-lok® ligating clip (SKU 544230), currently marketed by Teleflex Medical under 510(k) K133202.

The similarities and differences of the next generation Percuvance™ system compared to the predicate devices are presented in the following table.

Comparative Characteristics	Next Generation Percuvance™ System	Percuvance™ System	MiniLap® MiniPolar Electrocautery Instruments	Hem-o-lok® Ligating Clip System	Explanation of Differences
	K153063	**Predicate - K143299**	**Predicate – K083754**	**Reference – K133202**	
Handle	Yes	Yes	Yes, thumb grip Handle pre-assembled to Shaft and Instrument Tip as one finished component	N/A	Equivalent to K143299 and K083754
Shaft	Yes (2.9mm)	Yes (3mm)	Yes (2.4mm)	N/A	Equivalent to K143299 and K083754
Introducer Tip	Yes	Yes	Yes, pre-assembled to Shaft and Instrument Tip as one finished component	N/A	Equivalent to K143299 and K083754
Tool Tips	Yes (5mm)	Yes (5mm)	Yes, but not exchangeable; Tips pre-assembled to Shaft	N/A	Equivalent to K143299 and K083754
Tool Tip Attachment	Snap connection to Shaft over detents	Threaded to Shaft	Pre-assembled	N/A	Equivalent to K143299
Graspers	Yes	Yes	No	N/A	Equivalent to K143299
Maryland Dissectors	Yes	Yes	No	N/A	Equivalent to K143299
Scissors	Yes	Yes	No	N/A	Equivalent to K143299
Cautery Tips	Yes (Spatula and Hook)	No	Yes (Spatula, Hook, and Conical)	N/A	Equivalent to K083754
Clip Applier	Yes	No	No	Yes	Equivalent to K133202
Seal Bridges	Yes	Yes	No	N/A	Equivalent to K143299

Energy	Monopolar	No	Monopolar	N/A	Equivalent to K083754
Exchange Technology	Exchanged extra-corporeally	Exchanged extra-corporeally	Instrument Tips are pre-assembled to Shaft and not exchangeable	N/A	Equivalent to K143299

J. Materials

Patient contacting materials of the next generation Percuvance™ Percutaneous Surgical System have been evaluated in accordance with ISO 10993-1:2009, FDA Bluebook Memorandum G95-1 and FDA Draft Guidance: Use of International Standard ISO 10993.

Model Number	Component Description	Materials	Type of Contact
PCVINT3	Introducer Tool Tip	Stainless Steel	External Communicating Device with Tissue Contact for Limited Duration
PCVSC5	Scissors Tool Tip	Stainless Steel PEEK White Ink Lubricant	External Communicating Device with Tissue Contact for Limited Duration
PCVGG5	Gripper Grasper Tool Tip	Stainless Steel PEEK White Ink	External Communicating Device with Tissue Contact for Limited Duration
PCVJG5	Johans Grasper Tool Tip	Stainless Steel PEEK White Ink	External Communicating Device with Tissue Contact for Limited Duration
PCVMD5	Maryland Dissector Tool Tip	Stainless Steel PEEK White Ink	External Communicating Device with Tissue Contact for Limited Duration
PVCHK5	Hook Cautery Tool Tip	Stainless Steel PEEK White Ink	External Communicating Device with Tissue Contact for Limited Duration
PCVSPT5	Spatula Cautery Tool Tip	Stainless Steel PEEK White Ink	External Communicating Device with Tissue Contact for Limited Duration
PCVHCA5	Clip Applier Tool Tip	Stainless Steel PEEK White Ink	External Communicating Device with Tissue Contact for Limited Duration
PCVSH3	29cm Shaft	Stainless Steel PEEK PET PC	External Communicating Device with Tissue Contact for Limited Duration

		Green Ink	
PCVSHL3	36cm Shaft	Stainless Steel PEEK PET PC Green Ink	External Communicating Device with Tissue Contact for Limited Duration
PCVNRH	Non-Ratcheted Handle	Stainless Steel PEEK Nylon Medical Grade Epoxy	Surface Device with Skin Contact for Limited Duration
PCVRH	Ratcheted Handle	Stainless Steel PEEK Nylon Medical Grade Epoxy	Surface Device with Skin Contact for Limited Duration
PCVSB5	5mm Seal Bridge	Silicone Cyrolite	External Communicating Device with Tissue Contact for Limited Duration
PCVSB12	12mm Seal Bridge	Silicone Cyrolite	External Communicating Device with Tissue Contact for Limited Duration

K. Technological Characteristics

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

Both predicate systems and the next generation Percuvance™ Percutaneous Surgical System offer alternatives to traditional laparoscopic procedures, resulting in smaller incision sites to the abdomen. Like the existing Percuvance™ predicate system (K143299), the next generation Percuvance™ Percutaneous Surgical System includes a reusable Handle that connectors to a variety of interchangeable instrument tips, including Graspers, Scissors and Dissectors, which are used for the manipulation of soft tissue. Like the MiniLap® MiniPolar predicate system (K083754), the next generation Percuvance™ Percutaneous Surgical System includes Hook Cautery and Spatula Cautery instrument tips to apply monopolar RF energy.

The next generation Percuvance™ Percutaneous Surgical System also includes a Clip Applier Tool Tip, which utilizes technology equivalent to that of the M/L Hem-o-lok® manual, endoscopic clip applier 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.

L. Performance Data

Comprehensive bench testing has been successfully completed on Teleflex's Medical next generation Percuvance™ Percutaneous Surgical System. Similar to the predicate devices, the next generation Percuvance™ System was subjected to a variety of tests, including biocompatibility evaluation, functional verification, dimensional verification and force verification. Resulting data found that Teleflex Medical's next generation Percuvance™ Percutaneous Surgical System performed equivalently or better than the predicate systems.

Like the predicate Percuvance™ Percutaneous Surgical System (K143299), Teleflex Medical's next generation Percuvance™ Percutaneous Surgical System was evaluated for biocompatibility according to ISO 10993-1:2009, FDA Bluebook Memorandum G95-1 and FDA Draft Guidance: Use of International Standard ISO 10993. The following tests were performed on both the predicate Percuvance™ Percutaneous Surgical System (K143299) and the next generation Percuvance™ Percutaneous Surgical System. All tests were successful.

Model Number	Component Description	Type of Contact	Tests Conducted	Results
PCVINT3	Introducer Tool Tip	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass
PCVSC5	Scissors Tool Tip	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass
PCVGG5	Gripper Grasper Tool Tip	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass
PCVJG5	Johans Grasper Tool Tip	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass
PCVMD5	Maryland Dissector Tool Tip	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass
PVCHK5	Hook Cautery Tool Tip	External Communicating Device with Tissue Contact for	Cytotoxicity Intracutaneous Sensitization	Pass

		Limited Duration	Systemic Toxicity	
PCVSPT5	Spatula Cautery Tool Tip	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass
PCVHCA5	Clip Applier Tool Tip	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass
PCVSH3	29cm Shaft	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass
PCVSHL3	36cm Shaft	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass
PCVNRH	Non-Ratcheted Handle	Surface Device with Skin Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization	Pass
PCVRH	Ratcheted Handle	Surface Device with Skin Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization	Pass
PCVSB5	5mm Seal Bridge	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass
PCVSB12	12mm Seal Bridge	External Communicating Device with Tissue Contact for Limited Duration	Cytotoxicity Intracutaneous Sensitization Systemic Toxicity	Pass

Design verification testing for the next generation Percuvance™ Percutaneous Surgical System consisted of functional testing on the Handle, Shaft, Tool Tips and Seal Bridges. The Handles were exposed to repeated actuations, as well as durability studies. The Shafts underwent durability and strength testing, while the Tool Tips were evaluated for grip strength and tissue retention. The Clip Applier Tool Tip was tested for compatibility with the accessory ligating clip, and the Cautery Tool Tips were exposed to a variety of electrosurgical performance tests. Additionally, the Seal Bridges were exposed to insufflation leak prevention testing, and the entire system was evaluated for compatibility. All design verification testing results were acceptable.

Additional testing was conducted to compare the next generation Percuvance™ Percutaneous Surgical System's functionality to that of the predicate devices. Side-by-side bench testing compared the Clip Applier Tool Tip (SKU PCVHCA5) to the existing Hem-o-lok® Manual Endoscopic Clip Applier (SKU 544965, K133202). Tests evaluated trocar compatibility, clip formation and clip retention. The results of these tests demonstrate that trocar compatibility is equivalent and that there is not an increased incidence in poorly formed clips or poor clip retention when compared to the reference Clip Appliers.

Side-by-side testing was also conducted to compare the thermal effects of the next generation Percuvance™ Percutaneous Surgical System to that of the predicate devices in accordance with FDA Draft Guidance: Submissions for Electrosurgical Devices for General Surgery. This testing compared the thermal effects of the Maryland Dissector Tool Tip (SKU PCVMD5) to the thermal effects of the existing Pilling® Maryland Dissector (SKU 728014, K040855). Additionally, the Spatula Cautery Tool Tip (SKU PCVSPT5) and the Hook Cautery Tool Tip (SKU PCVHK5) were evaluated against the predicate MiniLap® MiniPolar Straight Spatula (SKU ECMS300, K083754) and L-Hook Probe (SKU ECMH300, K083754), respectively. As part of this testing, thermal effects were evaluated in three ex vivo soft tissue samples (chicken breast, beef liver and beef kidney) at minimum, default and maximum intensity settings for each type of activation (cut and coagulation). Thermal effects were measured and the dimensions (length, width and depth) of each thermal effect were compared to evaluate the thermal effects of each Tool Tip. Results of this testing concluded that the thermal effects of the next generation Percuvance™ Percutaneous Surgical System are equivalent to, or better than, the thermal effects of existing electrosurgical devices.

Design and usability validation testing of the next generation Percuvance™ Percutaneous Surgical System consisted of surgeons assembling the system, performing laparoscopic procedure steps in a porcine model and disassembling the system. The surgeons were guided without interference by a study director. Surgeons then completed a device usability questionnaire to evaluate the performance of the system. All design and usability validation testing results were acceptable.

During the porcine usability study, the surgeons also used both the Clip Applier Tool Tip (SKU PCVHCA5) and the existing Hem-o-lok® Manual Endoscopic Clip Applier (SKU 544965, K133202) to apply ligation in the porcine model. After ligation was applied, surgeons used a quantifiable score system to compare the compatibility with the trocar, clip security in the instrument during deployment, clip security in the instrument during tissue manipulation, feedback on closure, and lack of trauma during tissue manipulation and deployment. Results of this comparison conclude that the Clip Applier Tool Tip performs as well as the reference Hem-o-lok® Manual Endoscopic Clip Applier.

Like the predicate MiniLap® MiniPolar Electrocautery Instruments (K083754), the next generation Percuvance™ Percutaneous Surgical System is classified as an active

accessory, in accordance with AAMI/ANSI ES60601-1-:2005 (A1:2012). Based on this classification, the Percuvance™ System has been evaluated by a third party test house for electrosurgical safety and usability in accordance with the following applicable collateral and particular standards. All electrical safety and usability testing results were acceptable.

AAMI/ANSI ES60601-1:2005 (A1:2012) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (2nd edition and 3.1 edition)

AAMI/ANSI/IEC 60601-1-2:2014 Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests

IEC 60601-1-6:2010 (A1:2013) Medical Electrical Equipment -- Part 1-6: General Requirements For Basic Safety And Essential Performance -- Collaterial Standard: Usability

AAMI/ANSI/IEC 60601-2-2:2009 Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgery Equipment And High Frequency Surgical Accessories

IEC 60601-2-18:2009 Medical Electrical Equipment - Part 2-18: Particular Requirements For The Basic Safety And Essential Performance Of Endoscopic Equipment

ISO 8600-1:2013 Optics And Photonics -- Medical Endoscopes And Endotherapy Devices -- Part 1: General Requirements

ISO 8600-3:1997 (A1:2003) Optics And Optical Instruments - Medical Endoscopes And Endoscopic Accessories - Part 3: Determination Of Field Of View And Direction Of View Of Endoscopes With Optics

ISO 8600-4:2014 Optics And Optical Instruments -- Medical Endoscopes And Certain Accessories -- Part 4: Determination Of Maximum Width Of Insertion Portion

IEC 62366:2007 (A1:2014) Medical devices – Application of usability engineering to medical devices - Edition 1.0

Based on its intended use and active accessory classification, the next generation Percuvance™ System has been tested for high frequency dielectric strength and mains frequency dielectric strength. Additionally, the following electromagnetic

compatibility (EMC) testing was conducted on the next generation Percuvance™ System.

Emissions Testing (IEC 60601-1-2:2014)	
Standard and Test Description	Results
CISPR 11, Radiated Emissions (Class A)	Compliant
CISPR 11, Conducted Emissions (Class A)	Compliant
Immunity Testing (IEC 60601-1-2:2014)	
Standard and Test Description	Results
IEC 61000-4-3, Radiated Immunity	Compliant
IEC 61000-4-6, Conducted Immunity	Compliant

M. Conclusion

Based upon the testing and research presented throughout the submission and in this 510(k) Summary, Teleflex Medical's next generation Percuvance™ Percutaneous Surgical System is substantially equivalent in to the predicate devices cleared to market via 510(k) K143299 and K083754. The new design of the Percuvance™ Percutaneous Surgical System does not introduce any new issues of safety and effectiveness.