DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 21, 2015

Teleflex Medical Incorporated
Ms. Holly Hallock
Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, North Carolina 27709

Re: K143299
Trade/Device Name: Percuvance® Percutaneous Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 7, 2015
Received: January 8, 2015

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" (21CFR 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,

David Krause -S

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)*
Unknown K143299

Device Name
Percuvance® Percutaneous Surgical System

Indications for Use *(Describe)*
The Percutaneous Surgical System with 5 mm 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

Percuvance® Percutaneous Surgical System

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

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-4918
Fax: 919-433-4996

B. Contact Person

Holly Hallock
Regulatory Affairs Specialist

C. Date Prepared

January 16th, 2015

D. Device Name

Trade Name:	Percuvance® Percutaneous Surgical System
Common Name:	Laparoscope
Classification Regulation:	CFR 876.1500
Classification:	Class II
Panel:	General & Plastic Surgery
Product Code:	GCJ
Classification Name:	Endoscope and Accessories

E. Device Description

Teleflex Medical's proposed Percuvance® Percutaneous Surgical System is a micro-laparoscopic platform that comprises 9 unique components, which are combined in various configurations to create a multifunctional set of instruments for laparoscopic procedures. While this system is to be branded as Percuvance®, the specific portfolio name for this proposed platform is Teleflex Percutaneous Solutions.

System components include a reusable Handle, which is manipulated by the surgeon and connects to a Shaft. The Shaft affords various End Effectors to be attached in order to perform basic surgical manipulation.

Initial access to the surgical site is achieved with the Introducer End Effector attached to the Shaft. Once inside the patient, the Introducer End Effector is extracorporealized through a pre-inserted, central trocar and is then exchanged for one of the other End Effectors, which include Metzenbaum Scissors, Gripper Grasper, Johans Grasper and Maryland Dissector. 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 End Effectors.

F. Indications for Use

The Percutaneous Surgical System with 5 mm 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.

G. Contraindications

There are currently no known contraindications.

H. Substantial Equivalence

Teleflex Medical's proposed Percuvance® Percutaneous Surgical System is substantially equivalent to the predicate Sovereign® Mini Laparoscopic Surgical System:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Sovereign® Mini	Aesculap, Inc.	K123102	01/03/2013

I. Comparison to Predicate Devices

Teleflex Medical's proposed Percuvance® Percutaneous Surgical System is substantially equivalent to the predicate system with regards to technology, intended use and functional characteristics.

Both systems offer alternatives to traditional laparoscopic procedures, resulting in smaller incision sites. Like the predicate, the 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.

J. Materials

Patient contacting materials of the 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.

K. Technological Characteristics

A comparison of the technological characteristics of Teleflex Medical's 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.

Like the predicate device, the Percuvance® Percutaneous Surgical System is intended to manipulate tissue and includes components that introduce a variety of instrument configurations into the abdominal cavity with a smaller incision site than traditional laparoscopic surgery requires. Both systems offer reusable Handles that are compatible with interchangeable instrument tips, which include graspers, scissors and dissectors. However, unlike the predicate, the Percuvance® Percutaneous Surgical System affords a percutaneous incision into the patient without the use of a trocar.

L. Performance Data

Comprehensive bench testing, including functional verification, dimensional verification and force verification, has been successfully completed on Teleflex's Medical proposed Percuvance® Percutaneous Surgical System. Resulting data supports that Teleflex Medical's proposed Percuvance® Percutaneous Surgical System performed equivalent to the predicate system.

Design verification testing for the Percuvance® Percutaneous Surgical System consisted of functional testing on the Handle, Shaft, End Effectors and Seal Bridges. The Handles were exposed to repeated actuations, as well as durability studies. The Shafts underwent durability and strength testing, while the End Effectors were evaluated for grip strength and tissue retention. The Seal Bridges were exposed to insufflation leak prevention testing, and all components were evaluated for system compatibility. All design verification testing results were acceptable.

Design and usability validation testing of the Percuvance® Percutaneous Surgical System consisted of 14 surgeons assembling the device, performing laparoscopic procedure steps and disassembling the system in a porcine model. 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.

M. Conclusion

Based upon the testing and research presented throughout the submission and in this 510(k) Summary, Teleflex Medical's proposed Percuvance® Percutaneous Surgical System is substantially equivalent in to the predicate device cleared to market via 510(k) K123102. The new design of the Percuvance® Percutaneous Surgical System does not introduce any new issues of safety and effectiveness.