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

June 1, 2015

Sharp Medical Devices, LLC
% Ms. Melanie Cox
McFarlane Medical Incorporated
2571 Kaneville Court
Geneva, Illinois 60134

Re: K150549
Trade/Device Name: Reactor™ Trocar and Sleeve
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 9, 2015
Received: April 13, 2015

Dear Ms. Cox:

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,

Jennifer R. Stevenson -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)*
K150549

Device Name
Reactor™ Trocar and Sleeve

Indications for Use *(Describe)*
The Sharp Medical Reactor™ Trocar and Sleeve has indications in the creation of a port of entry into the thoracic cavity and allows the user to create and maintain limited access into the chest for the intention of chest tube placement.

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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5.0 510(k) Summary

Date	**April 9, 2015**		
Owner Operator	Sharp Medical Devices 7694 E. Rose Garden Lane Scottsdale, AZ 85255	**Preparer/ Contract Manufacture**	McFarlane Medical 2571 Kaneville Court Geneva, IL 60134 FDA No. 3006977040
Contact	Melanie Cox, Operations McFarlane Medical, Inc. 2571 Kaneville Court Geneva, IL 60134 Telephone (630) 208-8404, ext. 124 Fax (630) 232-8005		
Predicate Device	K935086 Visiport Plus, by United States Surgical		
Device Name	Reactor™ Trocar and Sleeve		
Proprietary Name	Reactor™		
Common Name	Surgical Trocar and Accessory		
Classification Name	Trocar and Accessories		
Classification	The classification for the Reactor™ Trocar with Sleeve is Trocar, General & Plastic Surgery, GCJ, classified in Class II, at 21 CFR 876.1500. This is a General and Plastic Surgery classification.		

Substantial Equivalence

The Reactor™ Trocar with Sleeve is substantially equivalent to the VISIPORT™ Plus RPF 5-12. The Reactor™ Trocar with Sleeve will have of the same intended use and the specifications are substantially equivalent to the predicate device. The Reactor™ Trocar with Sleeve poses no significant changes from the safety and efficacy of the predicate device.

	Subject Devices	**Substantially Equivalent Devices**
Product Description	Reactor™ Trocar with Sleeve	Visiport™ Plus
REF Number	100-36-01	176674P
510(k) Number	K150549	K935086
Intended Use	The device allows the user to create and maintain access for the intention of chest tube placement.	Unknown
Indications for Use	The Sharp Medical Reactor™ Trocar and Sleeve has indications in the creation of a port of entry into the thoracic cavity and allows the user to create and maintain limited access into the chest for the intention of chest tube placement.	The Visiport™ Plus optical trocar has indications in the creation of a port of entry into the abdominal or thoracic cavities during endoscopic procedures. The device allows the user to view passage of the trocar tip through the tissue layers of the abdominal or thoracic cavity wall.
Anatomical Sites	Thoracic cavity	Thoracic cavity
Where Used	Hospital	Hospital
Energy Used	N/A	N/A
Human Factors	Actuated by compressing trigger	Actuated by compressing trigger
Design		
Descriptive Size	Up to 12 mm	5 mm to 12mm
Length	100 mm	
Materials		
Sleeve	TEXIN RXT90A	Unknown
Trocar	ULTEM HU1004-8H8D264 LT GRAY	Unknown

Description of Device

The Reactor™ Trocar consists of an obturator with a flat tip at the distal end which encloses a circular scalpel shaped knife blade. The blade extends approximately 1mm and immediately retracts when the trigger is squeezed. The clear sleeve with printing accommodates instruments up to 36 Fr. or 12 mm.

Intended Use	The device allows the user to create and maintain access for the intention of chest tube placement.
Indication for Use	The Sharp Medical Reactor™ Trocar and Sleeve has indications in the creation of a port of entry into the thoracic cavity and allows the user to create and maintain limited access into the chest for the intention of chest tube placement.
Technological Characteristics	The technological characteristics of the subject device are the same as the predicate device**.** The device is a single use, sterile product compliant with ISO 11137 (Sterilization of Healthcare Products). It features a pistol grip with a squeeze-action trigger. The materials are biocompatible and comply with ISO 10993 (Biological Evaluation of Medical Devices).
Performance Data	Comparative performance testing between the subject device and the predicate device included a dry fire test, tissue insertion test, chest tube placement test, shaft rotation test, torque test, and surgical imitation tests in the TraumaMan surgical simulator. The bench tests confirm the performance of the Reactor™ Trocar and Sleeve is substantially equivalent to the predicate device and validate the Reactor™ Trocar and Sleeve perform as intended.
Conclusion	Based on the 510(k) summaries and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.