K103200

APR 12 2011

5. 510(k) Summary

Company Name:	Rhythmlink International, LLC 1140 First Street South Columbia, SC 29209 Phone: 803-252-1222 FDA Registration #: 1067162 Owner Operator #: 9052354
Official Contact Person:	James M. Mewborne Senior Engineer Rhythmlink International, LLC 1140 First Street South Columbia, SC 29209 Phone: 803-252-1222 ext. 101 Email: jmewborne@rhythmlink.com
Summary Date:	October 27, 2010
Device Identification:	**Proprietary Device Name:** Sterile Stainless Steel Introducer Needle/Cannula with Guide Base **Generic Device Name:** Surgical Guide Needle/General and Plastic Surgery, Cannula **Regulatory Class:** Class II **Classification Name:** 21 CFR 878.4800, Manual surgical instrument for general use. **Product Code:** MDM This device has not been previously submitted to the FDA.
Predicate Device(s):	510(k) Number: K013040 Manufacturer: MINRAD, Inc Trade Name: Light Saber™ Introducer Needle Product Code: MDM

Device Description:	The Stainless Steel Introducer Needle/Cannula with Guide Base is a single use disposable introducer needle/cannula intended for the precise placement of guide or needle wires, e.g., hook wires or EMG monopolar needles, in non-vascular laparoscopic procedures. The Introducer Needle/Cannula provides a temporary percutaneous guide to facilitate the placement of guide or needle wires, e.g., hook wires or EMG monopolar needles, into the abdominal cavity for surgical procedures and specifically for use during EMG monitoring. The Introducer Needle/Cannula with Guide Base has three main components: a Concentric Guide Tube, an Introducer Needle with Ring Hub and an Introducer Needle Guide Base. **Concentric Guide Tube:** The Concentric Guide Tube is permanently attached at the top of the Introducer Needle Guide Base and extends into the Introducer Needle. As the Introducer Needle is deployed this tube effectively telescopes out of the Introducer Needle and maintains a continuous concentric pathway from the integrated funnel at the top of the Concentric Guide Tube through the base and through the Introducer Needle. **Introducer Needle with Ring Hub:** The Introducer Needle with Ring Hub is made up of two parts: an advancement ring hub and a permanently attached stainless steel cannula needle which meets the recognized consensus standard ISO 9626 First edition. There is an alignment hole in the center of the Ring Hub that mates with the inner diameter of the Introducer Needle. The Guide Tube extends through this alignment hole into the Introducer Needle throughout the insertion and withdrawal procedure. **Introducer Needle Guide Base:** The Introducer Needle Guide Base is a molded cylindrical tube with a contoured face perpendicular to the tube. The contoured face has a biocompatible adhesive IAW ISO10993-1 and is used to stabilize the base when the device is placed on the patient. The cylindrical tube acts as a guide along which the Ring Hub slides during Introducer Needle Insertion and withdrawal.
Intended Use:	A single use disposable introducer needle/cannula intended for precise placement of guide or needle wires, e.g., hook wires or EMG monopolar needles, in non-vascular laparoscopic procedures.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Rhythmlink International, LLC
% Mr. James M. Mewborne
Senior Engineer
1140 First Street South
Columbia, South Carolina 29209

APR 12 2011

Re: K103200
Trade/Device Name: Sterile Stainless Steel Introducer Needle/Cannula with Guide Base
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF, MDM
Dated: March 15, 2011
Received: March 16, 2011

Dear Mr. Mewborne:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): **K103200**

Device Name: Sterile Stainless Steel Introducer Needle/Cannula with Guide Base

Intended Use:

A single use disposable introducer needle/cannula intended for precise placement of guide or needle wires, e.g., hook wires or EMG monopolar needles, in non-vascular laparoscopic procedures.

Indications for Use:

The Sterile Stainless Steel Introducer Needle/Cannula with Guide Base is indicated for use to provide temporary percutaneous placement of guide or needle wires, e.g., hook wires or EMG monopolar needles, during minimally invasive laparoscopic procedures.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103200