JAN 17 2014

1.0 510(k) SUMMARY: K133375

510(k) SUMMARY

Submitter:	Banyan Medical, LLC. 89 Bellows Street Warwick, RI 02888
Contact Person:	Tammy Healey, Quality Manager
Telephone:	401-383-9336
Fax:	401-228-7397
Establishment Registration#:	3009770724
510(k) Number:	K133375
Date 510(k) Prepared:	October 30, 2013
Proprietary Name:	Banyan Medical Disposable Secondary Cannula and Trocar for Laparoscopic Use
Common Name:	Cannula and Trocar
Classification:	876.1500
Product Code:	GCJ
Classification Name:	Laparoscope, General & Plastic Surgery
Substantial Equivalence Claimed To:	K911462; Apple Medical Surgical Trocar K112358; Unimax Secondary Trocar

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Device Description:

The Banyan Medical line of Disposable Secondary Cannula and Trocars for Laparoscopic Use consists of a trocar, cannula sleeve and a silicone seal. The design has two possible trocars, a sharp faceted tip and a conical tip. An insufflation adapter, when supplied, is compatible with standard luer lock fittings and provides for insufflation of the abdominal cavity. The Cannula and Trocar will be sold in 5mm, 8mm, 10mm and 12mm sizes.

Intended Use:

The Banyan Medical Disposable Secondary Cannula and Trocar for Laparoscopic Use is indicated for applications in abdominal and gynecologic minimally invasive laparoscopic surgical procedures to establish a port of entry for endoscopic and laparoscopic instruments. The trocar is used with visualization for secondary insertions.

Summary of Technological Characteristics:

The trocar consists of a threaded or press fit medical grade stainless steel tip attached to an anodized aluminum shaft that is insert molded or attached to a polycarbonate knob. The cannula is an Acetal copolymer molded component with integral thread design to improve retention to the abdominal wall. The cannula is assembled with a silicone seal to prevent loss of insufflation gas. All of the technological characteristics of the new device are the same as those of the predicate device.

Performance Data:

Non-Clinical Performance Data: The Banyan Medical Disposable Secondary Cannula and Trocar performance characteristics have been evaluated through non-clinical performance and bench testing (includes compression testing of the cannula, tensile testing of the knob to shaft of trocar, puncture testing of the trocar tip, shelf life testing and accelerated age testing, ship testing, and luer testing, which includes gauging, liquid leakage, air leakage, separation force, unscrewing torque, ease of assembly, resistance to overriding and stress cracking per ISO 594-1 and 594-2). The testing has demonstrated that the device performs as intended when used according to the instructions for use. The sterilization validation was performed according to the guidelines set forth in the standard ISO 11135:2007, Sterilization of health care products -- Ethylene

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oxide -- Part 1; Requirements for development, validation and routing control of a sterilization process for medical devices and ISO 10993-7:2008, Biological Evaluation for Medical Devices - Part 7: Ethylene Oxide sterilization residuals. A sterility assurance level (SAL) of $\geq 10^{-6}$ has been achieved.

The sterilization data submitted in this document meets the requirement set forth in the draft documents: Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labeled as Sterile.

Package and product integrity were tested in accordance with ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices and ASTM-F-1980-07(2011), Standard Guide for Accelerated Aging of Sterile Medical Device Packages.

The biocompatibility of the chosen materials was determined by the guidelines defined in ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process.

Clinical Performance Data: No clinical data is submitted.

Conclusions Drawn from Tests and Analysis:

The intended use and major performance parameters of the Banyan Medical Disposable Secondary Cannula and Trocar are similar or equivalent to the characteristics of the Apple Medical Disposable Trocar (K911462) and Unimax Secondary Trocar (K112358) as determined in section 12.0 of this Premarket Notification Traditional 510(k) submission.

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

Banyan Medical LLC
Ms. Tammy Healey
Quality Manager
89 Bellows Street
Warwick, Rhode Island 02888

January 17, 2014

Re: K133375
Trade/Device Name: Banyan medical disposable secondary cannula and trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 25, 2013
Received: November 27, 2013

Dear Ms. Healey:

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 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. 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,

Joshua C. Kipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.0 INDICATION FOR USE:

INDICATION FOR USE

510(k) Number (if known): K133375

Device Name: Banyan Medical Disposable Secondary Cannula and Trocar for Laparoscopic Use

Indications for Use:

The Banyan Medical Disposable Secondary Cannula and Trocar for Laparoscopic Use is indicated for applications in abdominal and gynecologic minimally invasive laparoscopic surgical procedures to establish a port of entry for endoscopic and laparoscopic instruments. The trocar is used with visualization for secondary insertions.

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

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003499056
Date: 2014.01.17 07:05:18 -05'00'

for BSA

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K133375
