K100045

JUN 2 5 2010

5. 510(k) Summary

[as required by 807.92(c)]

1. Applicant:dalim SurgNET Corporation

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Date: **2010-June-01**

2. Trade Name: OCTO™
3. Common Name: Laparoscopic Accessory
4. Classification Name: Endoscope and accessories
   Product Code: GCJ
   Regulation: 21 CFR 876.1500
   Class of device: Class II.
5. The legally marketed device to which we are claiming equivalence:
   K073719 ASC TriPort Laparoscopic Access Device
6. Description of device:
   The OCTO™ is a sterile, disposable laparoscopic instrument port which retracts a small abdominal incision to allow multiple laparoscopic instruments to pass through to the abdomen .
7. Intended Use:
   The OCTOTM is intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.
8. Technological Characteristics:
   The OCTO™ is a sterile, disposable laparoscopic instrument port which retracts a small abdominal incision to allow multiple laparoscopic instruments to pass through to the abdomen .
9. Performance data:
   1) Bench testing is performed to demonstrate the functionality and mechanical safety as following items;

a, comparative leak rate test to evaluate the leak rate without instruments, with instruments, and after vigorous manipulation of instruments vs. predicate device(s)
b, insufflation flow rate
c, insertion-withdrawal forces of instruments
d, determination of minimum size of skin incision
e, evaluation of OCTO™ Port device fixation

   2) Animal test is performed to demonstrate the ability for OCTOTM as following items
      a, ease of port insertion
      b, ease of instrument insertion and withdrawal
      c, ability to maintain pneumoperitoneum
      d, ability to manipulate instruments for laparoscopic surgery

f, ability to conduct a typical laparoscopic procedure: cholecystectomy
g, ability to hold OCTO™ Port in position during surgery

3) Equivalence comparison and difference are performed to demonstrate the technological characteristics the predicate as following items
- Equivalence comparison
a, device insertion procedure b, minimum length of skin incision
c, insertion device support mechanism, d, length of the device
e, number of flexible/rigid ports f, dimension of the access port,
g, angles of flexibility h, use with insufflation tubing and stopcock
- Difference
the no. of ports, and maximum device diameter.

The differences do not adversely affect the safety and effectiveness of OCTO™ Port

10. Conclusion:

The performance tests demonstrated that OCTO™ Port is as safe, as effective and performs in a substantially equivalent manner to the predicate device.

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

JUN 25 2010

Dalim SurgNET Corporation
% Mr. Peter Chung
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K100045
Trade/Device Name: OCTO™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 02, 2010
Received: June 11, 2010

Dear Mr. Chung:

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

K100045

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): ~~K09~~ K100045

Device Name: OCTO™

Indications For Use:

The OCTO™ is intended for use as a multiple instrument and/or camera port during minimally invasive abdominal laparoscopic surgery.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark RP Ogle for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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