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Section 10

510 (K) Executive Summary

AUG 3 0 2010

1. Submitter's Information

Company Name: Canada Endoscope Corporation
Company Address: 160 Konrad Crescent, Unit 4,
Markham, Ontario L3R9T9

Trade Name: 1) Cystoscope

Regulation Description: Endoscope and accessories

2. Predicate Device Identification

21 CFR 876.1500
Endoscope and Accessories
Product Code FAJ
Device Class II

3. Legally Marketed Equivalent Device

Asap Cystoscope (K031141)

4. Intended Use and Device Description

Like the predicate devices, the Canada Endoscope is used to visualize the body cavities, hollow organs and canals during diagnostic and therapeutic procedures, in conjunction with additional instruments. The intended use is the same as the predicate device.

The Canada Endoscope is a rigid type endoscope with a compact objectives and a developed rod-lens system. The basic design of the Canada Endoscope is similar to those legally available for sale in the USA. It consists of an eyepiece and the body with light guide and rod-lens system. The body is designed of an outer and an inner tube of surgical steel. The fiber optics (light carrying fibers) are located between these tubes. The inner tube of the body contains the rod-lens system.

5. Characteristics of the Device as Compared to Predicate Device

Characteristics	Current Device	Predicate Device (K031141)
Type	Cystoscope (Rigid)	Asap Cystoscope (Rigid)
Diameter	2.7 mm – 4.0 mm	2.7 mm – 4.00 mm
Working length	302 mm	302 mm

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Direction of View	0° - 70°	0° - 70°
Field of View	70°	70°
Instrument Connector	Storz	Storz
Light Cable Connector	ACMI, Wolf, Storz,	ACMI, Wolf, Storz,
Material (Body)	Stainless Steel 1.4301	Stainless Steel 1.4301
Sterilization	Autoclavable	Autoclavable
Weight	0.08 Kg	0.08 kg
Manufactured & Test	IS013485:2003 CMDCAS	EN13485:2003 CE

Conclusion

- The intended use of the Canada Endoscope is the same of the predicate device.
- The predicate endoscope device is presently in commercial distribution globally including the USA.
- The Canada Endoscope is similar in design, function, and application to the predicate device.
- The Canada Endoscope like the predicate device has no issues with safety or effectiveness.
- The Canada Endoscope body is designed of the same material to ensure biocompatibility as the predicate device. It also complies with applicable ISO standards.
- The device will be sold non-sterile, and to be sterile prior to each procedure by the user. Repeatability of sterilization has been confirmed by validation protocol.

6. Biocompatibility - No issues of biocompatibility are raised with the Canada Endoscope device.

7. Performance Testing - The device is similar in design and construction, and has the same intended use and performance characteristics to the predicate device. It utilizes materials that are already in use in the predicated devices. Like the predicate devices there are no issues with safety or effectiveness with the Canada Endoscope device.

The Canada Endoscope Cystoscope has been on the Canadian market since the year 2000 and is currently used at major hospitals such as Toronto General Hospital, Mount Sinai Hospital, Sunnybrook Hospital, St. Mikes Hospital, North York General Hospital, Sudbury Regional Hospital, Southlake Hospital, and Sick Kids Hospital Toronto.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Canada Endoscope Corporation
% Mr. Roger Leclerc
Director Regulatory Affairs
Medical Devices & Biosciences Int'l
1590 Oakburn Street
PICKERING ON L1V 6M9
CANADA

AUG 30 2010

Re: K093725
Trade/Device Name: Cystoscope Types: CE0004-C, CE0027-C, CE3004-C, CE3027-C, CE1204-C, CE1227-C, CE7004-C
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: August 19, 2010
Received: August 23, 2010

Dear Mr. Leclerc:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093725

Section 4
Indications for Use Statement
New 510(K) Submission

Indications for Use

510(k) Number (if known): K093725

Device Name:

a) Cystoscope Types: CE0004-C, CE0027-C, CE3004-C,CE3027-C, CE1204-C, CE1227-C, CE7004-C

Indications for Use:

Like the predicated devices, the Canada Endoscope is used to visualize the urinary tract for diagnostic and therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093725