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SECTION 3. 510(k) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness for CAD 12.

SUBMITTER'S NAME:	SoftScope Medical Technologies, Inc.
ADDRESS:	6110 Blue Circle Drive, Suite 220 Minnetonka, MN 55343
CONTACT PERSON:	Bernard (Bud) Horwath
TELEPHONE NUMBER:	651-481-9734
FAX NUMBER:	952-564-3914
DATE OF SUBMISSION:	July 15, 2009

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1. **Identification of device**
   Proprietary Name: CAD 12, Colonoscopy Assist Device
   Common Name: Overtube, Endoscopy Assist Device
   Classification Status: Class II per regulations 876.1500
   Product Codes: KOG

2. **Equivalent devices**
   SoftScope Medical believes that CAD 12 is substantially equivalent to the following predicate devices:

   Intended Use and Device Design:
   - Spirus Medical Endo-Ease Overtube, K052084
   - Fujinon EC-450 Double Balloon Overtube, K090116

   Rotating Drive Mechanism:
   - Boston Scientific Sonicath Ultrasonic Catheter, K970049/K060947
   - Olympus Ultrasonic Transducer, K982610/K063683

3. **Description of the Device**
   The CAD 12 is an endoscopic accessory device configured as an overtube to aid insertion and advancement of an endoscope. The CAD 12 utilizes a rotating membrane tube to advance the endoscope in the lower GI tract. The rotating membrane tube is driven by two mechanical rotating drive wires.

4. **Intended use**
   The CAD 12 is indicated for use with a flexible endoscope to aid endoscopic insertion and advancement during diagnostic and therapeutic lower gastrointestinal endoscopy.

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5. **Technological characteristics, comparison to predicate device.**
Like the Overtube predicate devices, CAD 12 has the same intended use and basic design intent. The CAD 12 is an overtube design, which is placed over the endoscope to aid in its insertion and advancement via a propulsion assist mechanism.
The CAD 12 propulsion drive cable is similar to the shaft of the Ultrasonic transducer predicates, using a mechanical rotating drive wire within a catheter sheath.

6. **Discussion of performance testing.**
An extensive collection of tests has been conducted and successfully completed, including functional performance, safety, biocompatibility and sterility testing. All testing indicates that CAD 12 meets its specification requirements.

7. **Conclusion**
Based on extensive performance testing and a comparison to the predicate devices, it is the conclusion of SoftScope Medical that CAD 12 is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

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

SoftScope Medical Technologies, Inc.
% Mr. Bernard Horwath
Consultant
Horwath Resource Group
4486 Timberline Court
VADNAIS MN 55127

OCT 14 2009

Re: K092156
Trade/Device Name: CAD 12 Colonoscopy Assist Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Dated: July 15, 2009
Received: July 16, 2009

Dear Mr. Horwath:

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.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 2. INDICATIONS for USE STATEMENT

510(k) Number K092156

Device Name: CAD 12

Indications for Use:

The CAD 12 is indicated for use with a flexible endoscope to aid endoscopic insertion and advancement during diagnostic and therapeutic lower gastrointestinal endoscopy.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092156