

K111480



APR - 4 2012

### Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Maxi-Flex Semi-Flex Scopes™.

**1. Company making the submission:**

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**2. Device Name:**

Trade/Proprietary Name:	Maxi-Flex Semi-Flex Scopes™
Common Name:	Endoscopes and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	FGB
Device Class:	Class II

**3. Predicate Devices:**

The Maxi-Flex Semi-Flex Scopes™ is substantially equivalent to the Maxi-Flex Semi-Flex Scopes [K062725] and ACMI DUR-8 [K023358].

**4. Indications for Use Statement:**

The MaxiFlex Semi Flex Scopes are intended to be used by trained medical professionals to examine the urinary tract, and using additional accessories, to perform various diagnostic and therapeutic procedures. Device may be re-used and re-sterilized by the EtO sterilization process up to 3 times



5. Description of Device:

The Maxi-Flex *Semi Flex Scopes*™ is flexible endoscope that allows operator-controlled deflection of the distal end or tip of the scope. The devices will be made available in lengths (25 cm and 65 cm), each length with a working channel. With a Maxi-Flex accessory a 'Y Port' the working channel may be utilized as an irrigation channel.

6. Testing:

**Maxi-Flex Semi-Flex Scopes™ (this submission), for reuse has been tested for four (4) EtO sterilization cycles without any degradation from original design specifications. All other core elements of K062725 remain unchanged.**

7. Rx or OTC:

The Maxi-Flex Semi-Flex Scopes™ is an Rx prescription device per 21 CFR Subpart D. The indication for use is for clinical setting only.

8. Conclusions:

The Maxi-Flex Semi-Flex Scopes™ is substantially equivalent to the predicate devices in the scope of practical application, effectiveness for this application, and ensuring the safety of its patient. This submission ad re-use to K062725.

The Maxi-Flex Semi-Flex Scopes™ with four (4) reuse cycles does not raise any new safety or effectiveness issues.

MaxiFlex, LLC

Gary Ventrella

Date: 03/31/12



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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Technology Delivery Systems, Inc.  
% Mr. James Harvey Knauss  
Contract Consultant  
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1516 Thalia Street  
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APR -4 2012

Re: K111480  
Trade/Device Name: MaxiFlex – Semi Flex Scopes  
Regulation Number: 21 CFR§ 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: FGB  
Dated: March 21, 2012  
Received: March 26, 2012

Dear Mr. Knauss:

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.

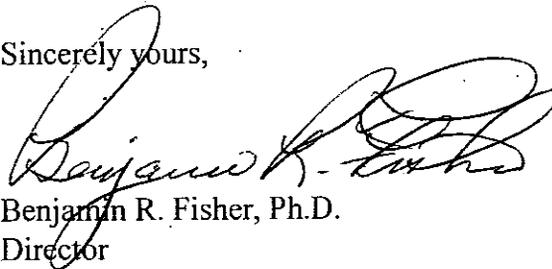
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Benjamin R. Fisher, Ph.D.  
Director

Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number: K111480

Device Name: **MaxiFlex – Semi Flex Scopes**

**Indications for Use:**

The MaxiFlex Semi Flex Scopes are intended to be used by trained medical professionals to examine the urinary tract, and using additional accessories, to perform various diagnostic and therapeutic procedures. Device may be re-used and re-sterilized by the EtO sterilization process up to 3 times

Prescription Use **YES**  
(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)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices  
510(k) Number K111480