



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

ACMI Corporation
Ms. Christine Nichols, RAC
136 Turnpike Road
Southborough, MA 01772-2104

JUL 27 2015

Re: K030684
Trade/Device Name: Scope Guard™ Protective Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCU, KCT
Dated (Date on orig SE ltr): March 4, 2003
Received (Date on orig SE ltr): March 5, 2003

Dear Ms. Nichols,

This letter corrects our substantially equivalent letter of June 3, 2003.

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,

Benjamin R. Fisher -S

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

V. Statement of Intended Use.

510(k) Number (if Known): _____

Device Name:

Scope Guard™ Protective Sheath

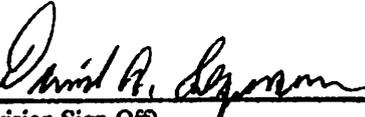
Indications For Use:

The Scope Guard protective sheath is intended for use during the transport, storage and sterilization of certain ACMI scopes for protection of these delicate instruments. It is not intended to be used alone for terminal sterilization but can be used in conjunction with an approved sterilization wrap to maintain sterility until the device is required for use. The ACMI scopes with Scope Guard can be wrapped, or placed into an approved sterilization tray for sterilization processing.

(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
(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030684



JUN - 3 2003

K030684

IV. Summary of Safety and Effectiveness

510(k) Summary for Scope Guard™ Protective Sheath

- A. Sponsor **ACMI CORPORATION**
 136 Turnpike Rd
 Southborough, MA 01772
- B. Device Name **Scope Guard™**
- C. Predicate Device **Polyvac Surgical Instrument Delivery System (K012105)**
- D. Device Description

The Scope Guard Protective Sheath is a polymer tube in various widths and lengths with evenly distributed holes along the length of the shaft. It is designed to snap onto ACMI telescopes for protection during storage and sterilization.

1. Intended Use

The Scope Guard protective sheath is intended for use during the transport, storage and sterilization of certain ACMI scopes for protection of these delicate instruments. It is not intended to be used alone for terminal sterilization but can be used in conjunction with an approved sterilization wrap to maintain sterility until the device is required for use. The ACMI scopes with Scope Guard can be wrapped, or placed into an approved sterilization tray for sterilization processing.

2. Technological Characteristics and Substantial Equivalence

The ACMI Scope Guard has been tested and compared to similar devices. The Scope Guard is substantially equivalent to the predicate described for the parameters tested.

3. Performance Testing

ACMI Scope Guards have been bench tested for durability, sterile efficacy and material compatibility with several sterilization methods.