JUN 19 1998

K981286
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ARMM, Inc.

17744 Sampson Lane
Huntington Beach, CA 92647
714-848-8190 Fax 714-848-6141

Submitter: Roger Wood

Date 04/06/98

2. SMDA Requirements:
510(K) Summary

.Trade name
Classification Name: Gastroenterology-urology devices
Proprietary Name: SuperFlow Irrigation and Aspiration Tubing Sets

. Common Name
Common Name: Gastrointestinal tube and accessories

. Device Class
The devices listed in this classification referenced in the Code of Federal Regulations (21 CFR 876.59800) are Class II classification number 78KDH.

. New or Modification
The devices listed in this 510(k) summary are modifications of the existing device called the EndoSI Suction/Irrigator previously approved with the 510(K) #K923201.
The safety and effectiveness of this device is substantially equivalent to that of the predicate device (The EndoSI Suction Irrigators) because the components are identical to those that have been used in the EndoSI Suction Irrigators. The biocompatibility of the device has been tested as part of the Suction Irrigators and has passed. This device is similar in design, composition and function to the EndoSI Suction Irrigator. The modification done is by removing the suction/irrigation trumpet valve unit from the corresponding tubing sets and selling the tubing sets for aspiration and irrigation by themselves for indications in general and gastrointestinal surgery not just laparoscopic surgeries. The tubing is offered in different sizes. There are no different technological characteristics of this device compared to the suction/irrigator.

The irrigation tubing sets are conduits for irrigant. One end is hooked up to the irrigant source and the other is hooked to a handle or accessory for flushing and washing.

The aspiration tubing sets are conduits for suction. One end is hooked up to the suction source while the other is hooked to a handle oraccessory for the removal of fluids, air and debris.

3. Proposed Labeling:

a.Package Labels

See Addendum I for a copy of the proposed label for the Irrigation Sets.
See Addendum II for a copy of the proposed label for the Aspiration Sets.

b. Statement of intended use

Irrigation Tubing Sets: This tubing set is for use with typical bag or bottle irrigation systems. Irrigate as desired. (Refer to the instructions for the irrigation system in use.)

Aspiration Tubing Sets: This tubing set is for use with typical aspiration systems. Aspirate as required. (Refer to the instructions for the aspiration system in use.)

c. Promotional Materials

See Addendum III for a copy of the promotional materials for the Irrigation Tubing Sets.
See addendum IV for a draft copy of the promotional material for the Aspiration Tubing Sets.

4. Description of Device:

The irrigation sets will be offered in different sizes with spikes and luer locks for attachments to the gravity bag feed systems. There would be four different size single line tubing sets to allow the customer to chose the most economical set according to what their requirements are. There would be one dual set with a wye and two pinch clamps to allow for the use of two supply bags. There would be one set offered with valves for the use of the bottle type supply systems so that clamps would not have to be activated for operation.

See Addendum V and Addendum VI for the Irrigation Set drawings.

The aspiration tubing sets will be offered in different sizes with suction connectors and luer locks for those smaller sizes that require them for hooking them to the suction system. The larger sizes may be used by just pushing the tubing over the barbed connectors on the suction supply systems.

See Addendum VII for the Aspiration Set drawings.

5. Comparison Information:

These products are similar in design, composition and function to existing marketed tubing sets. The tubing is identical to what is presently being supplied in the afore mentioned EndoSI suction/irrigation device. The aspiration tubing sets are similar in form and function to the suction tubing used on the EndoSI Suction Irrigator. The irrigation tubing sets are similar to the irrigation tubing used on the EndoSI Suction Irrigator.

See Addendum VIII for the EndoSI Suction/Irrigator with Tubing Sets compared to the proposed Irrigation Tubing Sets and Aspiration Tubing Sets.

6. Biocompatibility data or certification of identical material /formulation:

a. Component and materials

The components and the materials that are being utilized are identical to those that have been used in the EndoSI Suction/Irrigator. The tubing is made from the PVC tubing and all of the components will be either PVC, ABS or acrylic.

b. Patient contacting materials

The patient contacting materials will be the PVC tubing.

c. Biocompatibility

The tubing sets have been tested to be biocompatible.
See Addendum IX for the information.

7. Sterilization and expiration dating information:

a. Sterilization Method

Sterilization will be accomplished by Gamma Radiation (Cobalt 60). The sterilization process for the EndoSI Suction/Irrigator has been validated utilizing the guidelines issued by AAMI for Method I Radiation Sterilization.

This validation will apply to the irrigation and aspiration tubing sets. However, periodic audits will be undertaken for both of these tubing sets to assure the sterility on an ongoing basis.

The manufacturing date will be placed on the label instead of using an expiration date.

b. Sterility Assurance Level

The sterility assurance level will be 10(-6).

c. Packaging

The irrigation tubing sets will be pouched in standard mylar/tyvek pouches with a label placed on the exterior of the pouch. Units will be placed 10 units per box.

The Aspiration Tubing sets will be pouched in standard mylar/tyvek pouches with a label placed on the exterior of the pouch. Units will be placed 10 units per box.

d. Pyrogenicity

No claims on the non-pyrogenicity of the tubing sets will be made.

e. Radiation dose

Both of the irrigation and aspiration tubing sets will be processed on a production basis at 25 to 35 kGs. Periodic audits will be undertaken to assure conformance to applicable standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 1998

Mr. Roger Wood
ARMM, Incorporated
17744 Sampson Lane
Huntington Beach, California 92647

Re: K981286
Trade Name: SuperFlow Irrigation/Aspiration Tubing
Regulatory Class: II
Product Code: KDH
Dated: April 6, 1998
Received: April 8, 1998

Dear Mr. Wood:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981286

Device Name: SuperFlow Irrigation and Aspiration Tubing Sets

Indications For Use:

The irrigation tubing sets will be used to flush and instill fluids into sites so that visibility is maintained for the operating team. The sets will be attached to standard irrigation systems such as either gravity bag systems attached to I.V. poles or to standard pump systems that use pressurized bottles instead of the gravity fed bags as the source of the irrigant. The handle or accessory for irrigation would be attached to the end opposite the irrigant source.

The aspiration tubing sets will be used for the removal of fluids, air or debris left after or during the surgery. These sets could be used just to remove the flushing irrigant that is used to keep the surgical arena visible. One end would be attached to the suction source and the other end would be attached to the suction tip handle.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981286

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)