K983154
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MAY 5 1999

510(k) SUMMARY

510(k) NUMBER: K983154

SUBMITTED BY: Applied Medical Resources Corporation
26051 Merit Circle, Unit # 103
Laguna Hills, California 92653
(949) 582-6120

CONTACT PERSON: Anil Bhalani

DATE OF PREPARATION: February 1 1999

NAME OF DEVICE: Applied Medical Cystic Duct Balloon Dilating Catheter

CLASSIFICATION NAME: Endoscope and Accessories, 21 CFR 876.1500

TRADE NAME: Not Determined

SUMMARY STATEMENT: The Applied Medical Cystic Duct Balloon Dilating Catheter is indicated for dilating narrowed or obstructed ducts in the biliary tree to allow access for diagnostic or surgical procedures. The Applied Medical Cystic Duct Balloon Dilating Catheter is substantially equivalent to predicate devices cleared for marketing inclusive of the Applied Medical Obturator (dilator) which is a component of the Cystic Duct Access Kit K929224/A and the Cook Guided Biliary Dilator Set which is a pre-amendment device. The Applied Cystic Duct Dilator consists of a non-distensible dilating balloon with a inflation profile of 15 French.

The Applied Medical Cystic Duct Balloon Dilating Catheter passed all testing to demonstrate substantial equivalence to the predicate devices and introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 5 1999

Mr. Anil Bhalani
Director of Regulatory Affairs
and Clinical Programs
Applied Medical Resources
26051 Merit Circle, Building 104
Laguna Hills, California 92653

Re: K983154
Cystic Duct Balloon Dilating Catheter
Regulatory Class: II
21 CFR 876.5010/Product Code: 78 FGE
Dated: February 3, 1999
Received: February 4, 1999

Dear Mr. Bhalani:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director
Division of Reproductive, Abdominal,
Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applied Medical Resources is providing this **revised** separate cover page for the Applied Medical Cystic Duct Balloon Dilating Catheter "Indications for Use" as required.

510(k) Number: K983154

Device Name: Applied Medical Cystic Duct Balloon Dilating Catheter

Indications for Use: The Applied Medical Cystic Duct Balloon Dilating Catheter is indicated for dilating narrowed or obstructed ducts in the biliary tree to allow access for diagnostic or surgical procedures.

Signature: _____ Title: Director of RA and Clinical Programs Date: 2-3-99
ANIL BHALANI

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, ENT,
and Radiological Devices
510(k) Number K983154/S001