

K9774672

A. 510(k) Summary

MAR 13 1998

510(K) SUMMARY

SUBMITTER: Plastimed Laboratoire Pharmaceutique

CONTACT PERSON: Mr. Mike McCormick
 Plastimed, LLC
 212 3rd Avenue North, #446, Minneapolis, MN 55401
 Phone: 612-317-4550 Fax: 612-317-4554

DATE PREPARED: December 12, 1997

TRADE NAME: COMBICATH Double Plugged Telescoping Catheter

CLASSIFICATION NAME and NUMBER: Bronchoscope (flexible or rigid) and Accessories
 Class II, 21 CFR 874.4680

PRODUCT CODE: KTR

PREDICATE DEVICE(S): The COMBICATH Catheter is substantially equivalent to the BAL Cath (K923487), manufactured by Ballard Medical. Other similar devices include the Rigid Suction Tip (K822255), the Argyle Taussig Culture Catheter (K791327), and the Argyle DeLee Suction Catheter (K820572), made by other manufacturers.

DEVICE DESCRIPTION: The COMBICATH Catheter, is a radiopaque, double plugged, telescoping catheter designed to capture bronchoalveolar secretion samples in mechanically ventilated patients.

INTENDED USE: The COMBICATH Catheter Model 58216.27 is intended for use as a sampling tool by performing mini bronchoalveolar lavage in mechanically ventilated patients to obtain bronchoalveolar samples for laboratory testing and diagnosis.

The COMBICATH Catheter Models 58223.19, 58228.19, and 58229.19 are intended for use as sampling tools to capture protected distal bronchoalveolar samples from mechanically ventilated patients for laboratory testing and diagnosis.

FUNCTIONAL & SAFETY TESTING: Functional and safety testing of the COMBICATH Catheter consisted of examination of the function of the device under conditions similar to those found in normal usage and testing to ensure conformance to product specifications. The results of the examination and testing were successful, and did not raise any issues of safety and effectiveness of the device.

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CONCLUSION:

The COMBICATH Catheter is substantially equivalent to the BAL Cath (K923487), manufactured by Ballard Medical, based upon the devices' similarities in functional design, materials and indications for use.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mike McCormick
Plastimed L.L.C.
212 3rd Ave. North
Suite 446
Minneapolis, MN 55401

Re: K974642
Plastimed COMBICATH Catheter
Dated: December 12, 1997
Received: December 15, 1997
Regulatory class: II
21 CFR 874.4680/Procode: 77 EOQ

MAR 13 1998

Dear Mr. McCormick:

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 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, 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) 594-4613. 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,

Lillian Yin, Ph.D.
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 Page

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(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974642

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