K993720

JAN 1 8 2000

Summary of Safety and Effectiveness

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Cordis Maxi LD Large Diameter Balloon Dilatation Catheter	Esophageal Dilator

Name of Predicate Devices

The device is substantially equivalent to:

- Cordis Maxi LD PTA Balloon Catheter
- Boston Scientific XXL Balloon Dilatation Catheter

Classification

Class II.

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Indications for Use

The intended use of the Cordis Maxi LD Large Diameter Balloon Dilatation Catheter is for the dilatation of strictures of the esophagus.

Device Description

The device is an over the wire balloon catheter, with a distal balloon and a proximal hub. The balloon features two radiopaque marker bands.

Biocompatibility

All materials used in the Cordis Maxi LD Large Diameter Balloon Dilatation Catheter are biocompatible.

Summary of Substantial Equivalence

The Cordis Maxi LD Large Diameter Balloon Dilatation Catheter is substantially equivalent to the predicate devices. The equivalence was confirmed through pre-clinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2000

Ms. Ariel MacTavish, RAC
Manager Regulatory Affairs
Cordis Corporation
14201 N.W. 60th Avenue
Miami Lakes, FL 33014

Re: K993720
Cordis Maxi LD Large Diameter Balloon
Dilatation Catheter for the Esophagus
Dated: November 1, 1999
Received: November 3, 1999
Regulatory Class: II
21 CFR §876.5365/Procode: 78 KNQ

Dear Ms. MacTavish:

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. 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,

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 Statement

510(k) Number (if known) K993720

Device Name Cordis Maxi LD Large Diameter Balloon Dilatation Catheter

Indications for Use The intended use of the Cordis Maxi LD Large Balloon Dilatation Catheter is for the dilatation of strictures of the esophagus.

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 Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K993720

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)