

DEC 29 2000

A. *510(k) Summary*

SUBMITTER: Plastimed Laboratoire Pharmaceutique

CONTACT PERSON: Dr. Jean Daniel Nury
B.P. 20
2 Rue Loues Armand
Saint-Leu-La-Forêt Cédex 95321
France
Ph: 011 33 134 44 15 15
Fax: 011 33 1 30 72 22 08

DATE PREPARED: June 11, 1999

TRADE NAME: Seldiflex® central venous catheter

CLASSIFICATION NAME & NUMBER PRODUCT CODE: Long-term intravascular catheter
Unclassified
LJS

PREDICATE DEVICE(S): The Seldiflex® central venous catheter is substantially equivalent to the Hickman/Broviac central venous catheters manufactured by Bard Access Systems (K823553) and the ONECATH® long-term intravascular catheters manufactured by Luther Medical Products, Inc. (K980090), and other similar devices made by other manufacturers.

DEVICE DESCRIPTION: The Seldiflex® is a single lumen, radiopaque polyurethane, long-term central venous catheter. Its accessories include a protective adapter female cap, introducer needle, needle obturator, double-ended J guidewire, scalpel, catheter clamp, rigid fastener, a vessel dilator, and silver Dacron® cuff.

INTENDED USE: Plastimed's Seldiflex® central venous catheter is intended for long-term vascular access and is indicated for use with patients who require central venous pressure monitoring, I.V. fluids, blood products, drugs, or parenteral

nutrition solutions.

**FUNCTIONAL &
SAFETY TESTING:**

Functional and safety testing of the Seldiflex® central venous 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.

CONCLUSION:

The Seldiflex® central venous catheter is substantially equivalent to the Hickman/Broviac central venous catheters manufactured by Bard Access Systems (K823553) and the ONECATH® long-term intravascular catheters manufactured by Luther Medical Products, Inc. (K980090), and other similar devices made by other manufacturers based upon the devices' similarities in functional design, materials and indications for use.

B. Truthful and Accurate Statement

The Truthful and Accurate Statement is on the following page.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 29 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jean-Daniel Nury
General Manager
Plastimed Laboratoire Pharmaceutiqu
95321 Saint-Lue-La-Foret
Cedex,
FRANCE

Re: K992424
Trade Name: Seldiflex® Central Catheter
Regulatory Class: II
Product Code: LJS
Dated: October 6, 2000
Received: October 10, 2000

Dear Mr. Nury:

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 (Pre-market 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

Page 2 - Mr. Nury

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) 594-4692. 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" (21CFR 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,



Timothy A. Ulatowski *for*
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE PAGE

510(k) Number (if known): K992424

Device Name: Seldiflex® Central Venous Catheter

INDICATIONS FOR USE:

Plastimed's Seldiflex® central venous catheter is intended for long-term vascular access and is indicated for use with patients who require central venous pressure monitoring, I.V. fluids, blood products, drugs, or parenteral nutrition solutions.

Concurrence of CDRH, Office of Device Evaluation (ODE)

X Prescription Device

General W. Shupras
(Division Sign-Off) *per TAN*
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992424