

**Interpore Cross Manifold
With Extension Set**

**Interpore Cross International
- Confidential -**

510(K) SUMMARY

SUBMITTED BY

Lynn Rodarti
Manager, Regulatory Affairs
INTERPORE International
181 Technology Drive
Irvine, California 92618

(714) 453-3200

Date Submitted: July 2, 1998

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Stopcock, I.V. Set
Common/Usual Name: Stopcock Manifold
Product Classification: Class II
Proprietary Name: Manifold with Extension Set

PREDICATE DEVICE

Medex Guide-Flo Stopcock Manifold Gangs, Preamendment Device and
Baxter Stopcock Manifold Gangs, 510(k) K962531.

This summary of 510(k) safety and effectiveness information is being
submitted in accordance with the requirements of 21 CFR §807.92.

INDICATIONS-FOR-USE

The Interpore Cross International Manifold with Extension Set is intended to
provide multiple access sites into a common fluid path for blood, plasma or
solutions. The luer connectors on either end of the stopcock gang allow
connection to an Extension Set for fluid transfer (i.e., blood, plasma, or
solution).

DEVICE DESCRIPTION

The Interpore Cross Manifold with Extension Set consists of individual
stopcocks assembled in series through common luer fittings to form a
manifold or stopcock gang. These pre-assembled stopcock gangs provide
multiple access sites into a common fluid path for blood, plasma or solutions.

The luer connectors on either end of the stopcock gang (Manifold) allow connection to the Extension Set for fluid transfer. The backing plate can be used to attach the stopcock manifold gang to an IV pole.

COMPARISON TO THE PREDICATE DEVICE

The Interpore Cross Manifold with Extension Set is technologically substantially equivalent to the predicate devices in every respect.

DISCUSSION OF NONCLINICAL TESTS

Data regarding the functional performance of the proposed Manifold have been generated. Testing included ease of assembly, unscrewing torque, air leakage, liquid leakage, separation force, resistance to overriding, pressure seal testing, Manifold flow rate, mechanical security of stopcock gangs to backing plate. The data indicate that the proposed Manifold meets or exceeds all functional requirements and support its suitability for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 1998

Ms. Lynn Rodarti
Manager, Regulatory Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618

Re: K982368
Trade Name: Manifold with Extension Set
Regulatory Class: II
Product Code: FMG
Dated: July 6, 1998
Received: July 7, 1998

Dear Ms. Rodarti:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

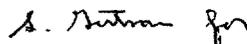
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (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,



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

Enclosure

510(k) Number (if known):

Device Name: Manifold with Extension Set

Indications-For-Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cicchetti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K 982368

Prescription Use
(PER 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)