K070143
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510(k) Summary of Safety and Effectiveness

APR 10 2007

1. Manufacturer and contact Information

1.1 Manufacturer

JMS Co., Ltd.
12-17 Kako-Machi, Naka-Ku
Hiroshima, Japan

1.2 Sponsor

JMS North America Corperation
22320 Foothill Blvd., Suite 350
Hayward, CA 94541
USA

1.3 Contact Information

Swee Cheau, Chong
Manager of RA & QA
JMS North America Corporation
22320 Foothill Blvd., Suite 350
Hayward, CA 94541
Telephone: (510) 888-9090
Fax: (510) 888-9099

2. Device Name

Common / Usual Name: PN Stopcock (PNSC)
Proprietary / Trade Name: JMS Planecta® Stopcock
Classification Name: Stopcocks, I.V. Sets
Panel : General Hospital
Product Code : FMG
Regulation : 21 CFR 880.5440

3. Device Intended use

JMS Planecta® Stopcock (PNSC) is indicated for fluid flow directional control and for providing access port(s) for administration of solutions, withdrawal of fluids and pressure monitoring. JMS Planecta® Stopcock can be used by itself, or as component to administration/extension set, and aids in the prevention of needle stick injuries

4. Predicate Device Name

JMS Planecta® device (510(k) 023668) is used as the predicate device because of the identical needleless access port design. Ohmeda Inc.'s Connecta® Plus 1 and Connecta® Plus 3 3-way Stopcock (510(k) 974083) is used to compare the characteristics and performance of three-way stopcocks.

JMS Planecta® Stopcock is substantially equivalent to the following predicate devices which are legally marketed with desired intended use, design, safety and effectiveness:

Table A: Comparison Matrix

Classification Name:	Stopcock, I.V. Sets	Intravascular Administration Set	
Device Type	Intended Device	Predicate Device	
510(k) Number	-	K023668	K974083
Proprietary Name:	JMS Planecta® Stopcock	JMS Planecta®	Connecta Plus 3-way Stopcocks
Device Classification:	21 CFR 880.5540	21 CFR 880.5540	21 CFR 880.5540
Classification:	Class II	Class II	Class II
Device Panel Code:	80	80	80
Device Product Code:	FMG	FPA	FMG

5. Device Description

The JMS Planecta® Stopcock is a disposable device for one time use. The device consists of a body with integrated female and male connector at extreme ends, a handle (either 1-bar or 3-bar types), pre-slit septum, access port cap and a rotatable lock nut for locking over the female connector of another component. The device contains three channels for fluid flow. The handle/swivel nut contains two independent passageways. A fluid pathway can be achieved by rotating the handle to one of the three channels. There are 'arrow' marks on the handle of 3-bar type and 'OFF' indication on the 1-bar handle to indicate the 'open' and 'closed' position of fluid path, respectively.

JMS Planecta® Stopcock, incorporated with an injection/sampling port accessible with a needleless syringe or regular male connector. JMS Planecta® Stopcock keeps the system closed and the minimal dead space at the access port reduces the chances of bacteremia caused by bacterial proliferation. Contamination by environmental microbes is also reduced by the resealability characteristics of the pre-slit rubber septum.

6. Technological Characteristics and Substantial Equivalence

The configurations, labeling, packaging, materials and mode of sterilizations of the JMS Planecta® Stopcock are similar to legally marketed predicate devices and are used for fluid flow directional control and for providing access port(s) for administration of solutions. The intended device and all other predicate devices are labeled sterile, non-pyrogenic and for single use only.

JMS Planecta® Stopcock demonstrates substantial equivalence to the said predicate devices with regards to intended use, material, biocompatibility, and overall performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Swee Cheau, Chong
Manager of Regulatory Affairs & Quality Assurance
JMS North America Corporation
22320 Foothill Boulevard, Suite 350
Hayward, California 94541

APR 10 2007

Re: K070143
Trade/Device Name: JMS Planecta® Stopcock (PNSC)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG
Dated: January 12, 2007
Received: January 16, 2007

Dear Mr. Chong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K070143

Device Name : JMS Planecta® Stopcock (PNSC)

Indications For Use:

JMS Planecta® Stopcock (PNSC) is indicated for fluid flow directional control and for providing access port(s) for administration of solutions, withdrawal of fluids and pressure monitoring. JMS Planecta® Stopcock can be used by itself, or as component to administration/extension set, and aids in the prevention of needle stick injuries.

(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 Section 801.109)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K070143