DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2003

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

Re: K023668
Trade/Device Name: JMS Extension Set with Planecta™, Planecta™ (stand Alone unit), Planecta™ Lock & Planecta™ Adaptor
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 8, 2003
Received: May 9, 2003

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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim 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:

Device Name : JMS Extension Set with Planecta™, Planecta™ (stand alone unit), Planecta™ Lock & Planecta™ Adaptor

Product Class / Classification : Class II

Product Code : FPA

Regulation Number : CFR 21 – 880.5440

Indications For Use: JMS Extension Set with Planecta™, Planecta™ (stand alone unit) and Planecta™ Lock / Adaptor are accessories and to be used with a primary vascular access device for fluid administration and blood sampling. Planecta™ will be connected with a luer slip syringe or male luer connector to allow needle-less access to the vascular path for injection or withdrawal of fluids or blood. Planecta™ Lock / Adaptor will be used as an adaptor for connection with luer lock syringe or other lock-connecting devices. These device accessories are intended for single use only.

JMS Extension Set with Planecta™, Planecta™ (stand alone unit) and Planecta™ Lock / Adaptor will reduce the risk of accidental needle stick injury as a needle will not be used or required throughout the procedure for injection or withdrawal of fluid.

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

510(k) Number: K023668