K120685

SEP 7 2012

510(k) SUMMARY

1. SUBMITTER INFORMATION:

Zyno Medical, LLC
10 Tech Circle
Natick, MA 01760, USA

Submitter Contact:
Mei Zhang, PhD
Engineering Manager
Phone: (508) 650-2008 Ext.205
Fax: (508) 650-2006
Email: mei.zhang@zynomed.com

2. NAME of DEVICE:

Trade Name: Zyno Medical Administration Set
Common Name: Intravascular Administration Set, Intravenous Administration Set, I.V. Administration Set, IV Set
Classification Name: Intravascular Administration Set

3. DEVICE CLASSIFICATION:

Device Class: II
Regulation Number: 21 CFR 880.5440
Product Code: FPA
Panel: General Hospital and Personal Use

4. PREDICATE DEVICES:

The Zyno Medical's Administration Set is substantially equivalent to the following predicate devices:

--Solution Administration Set, Baxter Healthcare Corporation (K981792)
--AMSURE I.V. Administration Set, Amsino International, Inc (K973107)
--IV Administration Set, Health Line International Corporation (K060352)

5. STATEMENT OF INTENDED USE:

The Zyno Medical Administration Set is a device used to administer fluids from a container to a patient's vascular system through a needle or a catheter inserted into a vein.

6. DEVICE DESCRIPTION:

The Zyno Medical's I.V. Administration Set is a single use, latex-free, non-DEHP device sterilized with Ethylene Oxide gas. It is utilized to administer fluids from a container to a patient's vascular system through a catheter or needle inserted into a vein.

Depending on configuration, the device may include the following components: tubing, protective cap(s), drip chamber (s) with spike, tubing, back check valve(s), needleless Y-site(s), slide clamp(s), roller clamp(s), pinch clamp(s), 0.22 micron filter or 1.2 micron filter, male luer lock (with cap), and pressure activated valve(s). Seven (7) representative administration sets and one (1) representative extension set are described in details in the application package to illustrate the device configurations.

Zyno Administration Set is identical to the following predicate devices:

-- IV Administration Set manufactured by Health Line International Corporation (K060352).
--AMSURE I.V. Administration Set, Amsino International, Inc (K973107)

Zyno medical currently privately labels the above administration sets for use with Zyno Medical's Z-800 family infusion pump (K100705).

7. SUMMARY OF TECHNOLOGY CHARACTERISTICS

Zyno Medical Administration Set is constructed of high grade extruded DEHP-free Polyvinyl Chloride (PVC). The primary components of Zyno Medical's Administration Set are manufactured to identical or similar specifications of the predicated devices listed above. The intended use, basic design, function and materials used are identical or similar to the predicate devices. The technical characteristic is substantially equivalent to the predicate devices. For details please refer to the Equivalency Table in the application package.

8. SUMMARY NON-CLINICAL TESTING

The non-clinical testing consisted of evaluation studies of the Zyno Medical Administration Set to verify its ability to meet its intended use requirements. This testing also included testing to the relevant safety standards. When appropriate, predicate devices were tested using the exact same method and sample size, for direct comparison of results. The data obtained from bench testing, sterilization testing, and biocompatibility testing showed that the device is substantially equivalent to the predicated device and complies with the safety and effectiveness criteria.

9. SUMMARY OF CLINICAL EVALUATION

A summary of clinical data has been provided to support that the Zyno Medical Administration Set is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 7 2012

Mr. Chaoyoung Lee
President
Zyno Medical Limited Liability Company
10 Tech Circle
Natick, Massachusetts 01760

Re: K120685
Trade/Device Name: Zyno Medical Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 26, 2012
Received: August 3, 2012

Dear Mr. Lee:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
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

510(k) Number (if known): K120685

Device Name: Zyno Medical Administration Set

Indications for Use:

The Zyno Medical Administration Set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C Chapman 8/30/12

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

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