K132841

JAN 2 3 2014

SPECIAL 510(K) SUMMARY

Submitted By:
Chaoyoung Lee, PhD
President / CEO
Zyno Medical, LLC
177 Pine Street
Natick, MA 01760, USA
Fax: 508-650-2006
Phone: 508-650-2008 x 103
Email: cylee@zynomed.com

Company Contact:
Mei Zhang, PhD
Director of Engineering
Zyno Medical, LLC
177 Pine Street
Natick, MA 01760, USA
Fax: 508-650-2006
Phone: 508-650-2008 x 205
Email: mei.zhang@zynomed.com

Date Originated: September 6, 2013
Establishment Registration No: 3006575795
Device Proprietary Name: Zyno Medical Administration Sets
Device Common, Usual or Classification Name: Intravascular Administration Set
Device Class: Class II
Panel: 80 General Hospital
Procodes: FPA 880.5440

Predicate Device
Zyno Medical Administration Sets (K120685, September 2012)

I. INTENDED USE

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.

The intended use of the modified device is the same as the predicate device.

II. DEVICE DESCRIPTION AND COMPARISON

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.

Zyno Medical LLC is submitting this **Special 510(k): Zyno Medical Administration Sets** to request a modification to our currently marketed administration sets. The major modifications are: 1) extended selection of interchangeable components manufactured by additional suppliers; 2) additional contract manufacturer for the device; 3) Gamma Irradiation as additional sterilization method. Verification and validation results support that the device is as safe and effective as the predicate device. We believe this application is eligible for the Special 510 (k) process since they have the same fundamental scientific technology and intended use as the predicate device. The principles of operation, intended use and the applications remain the same.

III. SUMMARY OF NONCLINICAL TESTING

Zyno Medical performed extensive verification and validation testing with the Zyno Medical Administration Set with modifications listed in above section II. Testing was completed in accordance with *Guidance for Industry and FDA Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)]* issued on July 11, 2008. In planning for bench testing to ensure proper functions and safety when used with the intended infusion pumps, *Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions.* issued on April 23, 20 10 was used as a reference.

Below is a summary of the nonclinical testing and evaluation performed. All results successfully met acceptance criteria:

A. Biocompatibility testing
B. Pyrogenicity testing
C. Chemical testing
D. Microbial ingress evaluation
E. DEHP testing
F. Sterilization testing
G. Bench testing, including integration testing with Z-800 series infusion pumps, physical and mechanical testing
H. Aging testing

Conclusion of Nonclinical Testing

All nonclinical testing results successfully demonstrated that the Zyno Medical Administration Sets performed as intended. Conclusions drawn from the nonclinical

testing is that the testing data demonstrated that the device is as safe, as effective, and performs as well as the legally marketed device cleared in K120685.

IV. CLINICAL STUDY

Human clinical studies were deemed unnecessary to evaluate the safety or effectiveness of the Zyno Medical Administration Sets.

V. STATEMENT OF EOUIVALENCE

The Zyno Medical Administration Sets are substantially equivalent to the predicate devices, based on comparisons of the device classifications, intended use, and technological characteristics. Verification and validation tests confirmed the suitability of the devices for their intended uses. The test results did not raise any safety or performance questions, and confirmed that the Zyno Medical Administration Sets are substantially equivalent to the predicate device.

The equivalency matrix (Table 1) compares the modified device with the predicate device (K120685).

Table 1: Equivalency Matrix

Parameter	Zyno Administration Set (Submitted in this package)	Zyno Administration Set (K120685)
Device Type	Administration Set	Administration Set
Intended use	To administer fluids from a container to a patient's vascular system through a needle or a catheter inserted into a vein.	To administer fluids from a container to a patient's vascular system through a needle or a catheter inserted into a vein.
Tubing material	Approved Standard PVC	Approved Standard PVC
Single use?	Yes	Yes
Sterile	Yes	Yes
ISO 8536-4:2010 compliant?	Yes	Yes
ISO 10993 compliant?	Yes	Yes
Operation mode	For use with Z-800 series of infusion pumps or gravity feed	For use with Z-800 series of infusion pump or gravity feed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 23, 2014

Zyno Medical LLC
C/O Mei Zhang
Director of Engineering
177 Pine Street
Natick, MA 01760

Re: K132841
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: December 20, 2013
Received: December 24, 2013

Dear Ms. Zhang:

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,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132841

Device Name
Zyno Medical Administration Sets

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.01.22 14:07:30 -05'00'

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