K112204

SEP 10 2012

Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: Jul 10, 2011

2. Sponsor
   Shanghai Kindly Enterprise Development Group Co., Ltd.
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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
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4. Proposed Device Identification

   Proposed Device Name: KDL Disposable Infusion Set
   Classification: II
   Product Code: FPA
   Regulation Number: 21 CFR 880.5440
   Review Panel: General Hospital
   Intended Use Statement:
   KDL Disposable Infusion Set is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

5. Predicate Device Identification

510(k) Number: K083687
Product Name: BAIXIN™ Intravascular Administration Set
Manufacturer: Anhui Kangda Medical Products Co., Ltd.

6. Device Description

The proposed device, KDL Disposable Infusion Set, is intended to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

The proposed device consists of protective cap, air filtration membrane, air-inlet set, closure-piercing device, drip chamber, medicine fluid filter, locked clamp, tubing, check valve, flow regulator, clamp, injection sites, two-part luer lock connector, infusion needle.

The protective cap is intended to protect the needle; the closure-piercing device is used to pierce the container; the drip chamber is transparent so that the user can observe the dropping condition of the medical solution, it has an air filtration membrane which can filter the air into the container and an air-inlet set which can control the air into the container and a medicine fluid filter which can filter the medical solution; the locked clamp is used to control the flow of the medicine solution; the tubing is used to connect various components; the check valve is used to make the medicine solution flow in one direction; the flow regulator is used to adjust the flow rate from zero to maximum; there are two injection sites, one is needleless and the other is needle access, which are used to inject solution into the tubing; two-part luer lock connector is used to connect the infusion needle with the tubing; infusion needle is inserted into human vessel for medical solution transfusion and it is made of stainless steel.

It is provided EO sterilized.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 8536-4: 2010, Infusion Equipment for Medical Use, Part 4: Infusion sets for single use, gravity feed
ISO 594-1:1986 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment, Part 1: General requirements
ISO 594-2 Second edition 1998-09-01, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings.

8. Substantially Equivalent Conclusion

The proposed device, KDL Disposable Infusion Set, is determined to be Substantially Equivalent (SE) to the predicate device, BAIXIN™ Intravascular Administration Set, in respect of safety and effectiveness.

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 10 2012

Shanghai Kindly Enterprise Development Group Company, Limited
C/O Mid-Link Consulting Company, Limited
Ms. Diana Hong
General Manager
P.O. Box 237-023
Shanghai, China 200237

Re: K112204
Trade/Device Name: KDL Disposable Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: August 31, 2012
Received: September 4, 2012

Dear Ms. Hong:

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

Section II Indications for Use

510(k) Number:
Device Name: KDL Disposable Infusion Set

Indications for Use:

KDL Disposable Infusion Set is indicated to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the vein.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(2 1 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)

9/10/12

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

510(k) Number: K112204