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510(K) SUMMARY

JUL - 2 2009

Submitted by:

Anhui Kangda Medical Products Co., Ltd.

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Preparation Date: Jun. 10. 2008

Contact Person/Prepared by:

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510(K) Summary of Safety and Effectiveness for the:

Trade/Proprietary Name: BAIXIN™ Disposable Syringe, Multiple Sizes

Common Name: Piston Syringe, Hypodermic

Classification Name: Piston Syringe

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Class: II

Panel: 80

Procodes: FMF - Piston Syringe FMI - Hypodermic Single Lumen Needle

Device Description:

BAIXIN Disposable Syringe is a device intended for medical purposes, consisting of a calibrated hollow barrel and a movable plunger. At one end of the barrel there is a male Luer Lock connector (nozzle) for attaching the female Luer connector (hub) of a hypodermic single lumen needle, or for attaching other devices with a female Luer.

Intended Use:

The intended use of the BAIXIN Disposable Syringe is to inject fluids into or withdraw fluids from the body.

Statement to conform to ISO 7886-1; 1993

Anhui Kangda Medical Products Co., Ltd. has established that its family of syringes corm to the FDA recognized consensus standard, ISO 7886-1:1993, *Sterile hypodermic syringes for single use - Part 1: Syringes for manual use.* Data supporting conformance with the standard is available from Anhui Kangda Medical Products Co., Ltd.

Summary of Testing:

All materials used in the fabrication of the Anhui Kangda piston syringe and hypodermic needles were evaluated for:

Testing Items	Code Requirement
Syringe Column Sealing	300 Kpa Positive Pressure – No leakage 88 Kpa Negative Pressure – No leakage
Volume	±4%
Tip Sealing Property	No Leakage
Indicating Ruler - 0 level line	Within 1/4 range
Tip Size Draw Strength	No separation at 25N
Residue Contents	< 0.075 cc
Sliding Property	Average < 10N
Appearance	Clean, Smooth
Non-bacteria	Non-bacteria
Pyrogen	Pyrogen-free

Toxicity	Non-toxic, no toxicity reaction for human body

Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate device are substantially equivalent and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2009

Anhui Kangda Medical Products Company, Limited
C/O Mr. Bian Wei Qiang
Shanghai Carelife International Trading Company, Limited
1707 Yinqiao Building
58 Jinxin Road
Jinqiao, Pudong, Shanghai
CHINA 201206

Re: K083686
Trade/Device Name: BAIXIN™ Disposable Syringe, Multiple Sizes (BAIXIN™)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF, FMI
Dated: June 3, 2009
Received: June 3, 2009

Dear Mr. Qiang:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Susan Runner, D.D.S., M.A.
Acting 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): K083686

Device Name: BAIXIN™ Disposable Syringe, Multiple Sizes (BAIXIN™)

Indications for Use: The intended use of the BAIXIN Disposable Syringe is to inject fluids into or withdraw fluids from the body.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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