K113247

MAR 2 7 2012

510(k) Summary

1. Submitter's Identification:

KI works Co., Ltd.

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Gyeongnam, Korea

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2. 510(k) Preparer

Company name: BSR KOREA Corp.

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Tel: +82-42-476-2977, Fax: +82-42-476-2978

Name of contact person: Eileen Yang

3. Identification of the device

Trade name / proprietary name: Anesthesia Injection Tool Set

Model No.: KIW-1000

Common / usual name: Anesthetic delivery device

Classification name: Cartridge syringe

Regulation number: 872.6770

Product code: EJI

4. Equivalent legally marketed device

The KI works' Anesthetic Injection Tool Set (KIW-1000) is substantially equivalent, with respect to questions of safety and effectiveness, to;

Predicate Device 1 - K002387 Comfort Control Syringe System

5. Intended use of the device

The device is indicated for the injection of local anesthetics for anesthesia administered prior to, or in conjunction with, dental procedures.

6. Description of the device

KI works' Anesthesia Injection Tool Set (KIW-1000) is a device for injecting local anesthetic for anesthesia prior to, or in conjunction with, dental procedures. This device consists of Main body, Hand-piece, Battery pack and Adapter. All operating displays and the majority of the operator controls are located on front panel of the control unit.

7. Safety and Effectiveness, comparison to predicate device

This subject device, KI works' Anesthesia Injection Tool Set (KIW-1000), and predicate device are substantially equivalent and have the same intended use. Technological and performance difference do not raise any new questions of safety or effectiveness. Comparison analysis, including comparison tables, of the subject device versus the predicate device is provided in section 7.Comparison chart.

8. Comparison chart

Section	Predicate Device DENTSPLY Professional(U.S.A.)	KIWORKS Co., Ltd.
Product name	MIDWEST Comfort Control Syringe	KIW-1000 (e-joa)
Web Address	www.dentsply.com	www.kiworks.co.kr
Intended Use	For the injection of local anesthetics for anesthesia prior to, or in conjunction with, dental procedures.	For the injection of local anesthetics for anesthesia administered prior to, or in conjunction with, dental procedures
Indications for use	To administer consistent and comfortable injections.	To deliver anesthetics in dental procedure safely and effectively without pain for patient.

Target	Anesthesia prior to, or in conjunction with, dental procedures	Anesthesia prior to, or in conjunction with, dental procedures
Point of use	Dental clinic	Dental clinic
Performance	To control motor by program to inject anesthetic safely and effectively. It will alleviate the patient's pain.	To control motor by program to inject anesthetic safely and effectively. It will alleviate the patient's pain.
FDA clearance	K002387 Class II	
Sterility	All the system is not contact with human body. Using in conjunction with disposable, one time use, standard syringe and needle.	All the system is not contact with human body. Using in conjunction with disposable, one time use, standard syringe and needle.
Control of anesthesia- time	Free control (High/Low speed)	Free control (High/Low speed)
anesthesia time	Small doses Short time	Small doses Short time
Source of Electric power	Internal	Internal Battery
operation	Automatic/Manual (5step speed control)	Automatic/Manual (6step speed control)

9. Statement of substantial equivalence

Please refer to the electrical test report and performance test report.
This device, Anesthesia Injection Tool Set (KIW-1000) is very similar with predicate device, DENTSPLY Professional.

Section	Predicate Device DENTSPLY Professional(U.S.A.)	KIWORKS Co., Ltd.
Product name	MIDWEST Comfort Control Syringe	KIW-1000 (e-joa)
Web Address	www.dentsply.com	www.kiworks.co.kr

Injection mode	**5mode button** -Block -Infiltration -Palate -PDL -intraosseous	**3 Mode** Auto1 Auto2 Manual 6 phases
Similarity	-An electronic pre-programmed anesthetic delivery device -Use a motor to control the injection flow speed	

10. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows: Testing information demonstrating safety and effectiveness of the Anesthesia Injection Tool Set (KIW-1000) in the intended environment of use is supported by testing that was conducted in accordance with EN60601-1, EN60601-1-2, EN55011:2007 and performance test (Bench). Both KIWORKS device and predicate device have first slow rate injection time in which the patient gets some degree of anesthesia. So for the performance test report, initial slow injection time was performed with predicate device. First slow injection time of Auto 1, KIW-1000 is similar to Predicate device's first 10 seconds. Auto 1 is designed for adult and Auto 2 is for children. For the children the first slow injection time is 22 second.

None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazards.

11. Discussion of Clinical Tests Performed:

Clinical testing was not conducted.

12. Conclusions:

Based on the information provided in this submission we concluded that the Auto controlled injection system is substantially equivalent to the predicate and is safe and effective for its intended use. Technological and performance difference do not raise any new questions of safety or 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

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C/O Ms. Eileen Yang
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C-Dong 524 #533-1
Yongsan-Dong, Daejeon
Republic of Korea KS

MAR 2 7 2012

Re: K113247
Trade/Device Name: Anesthesia Injection Tool Set Model No. KIW-1000
Regulation Number: 21 CFR 872.6770
Regulation Name: Cartridge Syringe
Regulatory Class: II
Product Code: EJI
Dated: March 16, 2012
Received: March 16, 2012

Dear Ms. Yang:

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

K113247

Indications for Use

510(k) Number (if known):

Device Name: Anesthesia Injection Tool Set Model No. KIW-1000

Indications for Use:

The device is indicated for the injection of local anesthetics for anesthesia administered prior to, or in conjunction with, dental procedures.

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)

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

510(k) Number: K113247