K123695

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Saeshin Precision Co., Ltd.
#93-15, Paho-Dong, Dalseo-Gu, Daegu, 704-220, Republic of Korea
Tel 82 53-587-2345 Fax 82 53-587-2347

510(k) Summary

DEC 1 8 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: December 26, 2011

1. Company and Correspondent making the submission:

	Company
Name	Saeshin Precision Co., Ltd.
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Phone	+82 53-587-2345
Fax	+82 53-587-2347
Contact	Y. S. Lee

2. Device:
   Proprietary Name – TRAUS SIP10
   Common Name – Dental handpiece and accessories
   Classification Name – Controller, Foot, Handpiece And Cord

3. Predicate Device:
   ImplantMED SI-915/923, K052741
   Surgical Contra-Angle Handpiece WS-75E/KM, K011061

4. Classifications Names & Citations:
   EBW, EGS, 21CFR872.4200

5. Description:
   The TRAUS SIP10 is an AC-powered device that includes a hand-held motor, controller, contra angle handpiece and foot controller for regulation of speed and direction of rotation or a contra-angle attachment for dental implant surgery.

6. Indication for use:
   The TRAUS SIP10 is intended for use in dental surgery, implantology, maxilla-facial surgery and endodontics for treatment of dental hard tissue and mechanical rotating root canal preparation.

7. Review:
   The TRAUS SIP10 has the same device characteristics as the predicate device;

indication for use, material, design and use concept are similar.

The biocompatibility of the patient contact parts has been demonstrated through the cytotoxicity, sensitization and irritation testing by ISO 10993-1 Biological evaluation of medical devices – Part1 Evaluation and Testing within a risk management process.

The TRAUS SIP10 conforms to IEC 60601-1 Medical electric equipment, Part 1: General requirements for safety and IEC 60601-1-2 Medical electric equipment, General requirements for safety collateral standard electromagnetic compatibility.

Based on the comparison of intended use and technical features, the TRAUS SIP10 is substantially equivalent to the predicate device.

8. Conclusions:
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Saeshin Precision Co., Ltd. concludes that the TRAUS SIP10 are safe and effective and substantially equivalent to predicate devices as described herein.

9. Saeshin Precision Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

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

December 18, 2012

Saeshin Precision Company, Limited
C/O Mr. Jeffrey D. Rongero
Senior Project Engineer
Underwriters Laboratories, Incorporated
12 Laboratory Drive
RESEARCH TRIANGLE NC 27709

Re: K123695
Trade/Device Name: TRAUS SIP 10
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKY
Dated: October 31, 2012
Received: December 3, 2012

Dear Mr. Rongero:

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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 123695

Device Name: TRAUS SIP10

Indication for use:

The TRAUS SIP10 is intended for use in dental surgery, implantology, maxilla-facial surgery and endodontics for treatment of dental hard tissue and mechanical rotating root canal preparation.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.12.18 11:50:08 -05'00'

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

510(k) Number: _____