..... we make smile
Jeil Medical Corporation

#702, Kolon Science Valley 2nd, 811
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Tel : +82 2 850 3500 / Fax : +82 2 850 3535

510(k) Summary K10 1902

FEB - 8 2011

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

Date: October 7, 2010

1. Company and Correspondent making the submission:

	Company
Name	Jeil Medical Corporation
Address	#702, kolon science valley 2nd 811, Guro-Dong, Guro-Gu Seoul, Republic of Korea 152-050
Phone	+82 2 850-3544
Fax	+82 2 850-3525
Contact	Jieun Kim

2. Device:
   Proprietary Name – J - Tac
   Common Name – Membrane fixation pin
   Classification Name – Screw, fixation, intraosseous

3. Predicate Device:
   The AutoTac System Titanium Tack, K022790

4. Classifications Names & Citations:
   DZL, CFR872.4880, Class 2

5. Description:
   The J - Tac is a metal device intended to stabilize a barrier membrane. It is made of Titanium Alloy and supplied non-sterile.

6. Indication for use:
   The J - Tac is intended to fixate and stabilize bioresorbable and non-resorbable barrier membranes used for regeneration of tissue in the oral cavity or in dental situations that require membrane use or fixation.

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7. Non-clinical testing data

Bench testing was conducted to confirm that the J – Tac has the safe and effective physical properties through the compression force test and torsion test. The testing result meets the requirements of its pre-defined acceptance criteria and intended uses.

8. Review:

The J - Tac has the same device characteristics as the predicate device, the AutoTac; intended use, material, design and use concept are similar.

The differences between them are the dimension of the tack, compression strength, torsion strength, etc.

Based on the comparison of intended use and technical features, the J - Tac is substantially equivalent to the predicate device.

9. 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 Jeil Medical Corporation concludes that the J tack are safe and effective and substantially equivalent to predicate devices as described herein.

10. Jeil Medical Corporation 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Jeil Medical Corporation
C/O Ms. Cathy Cambria
Arkin Consulting Group
1733 Canton Lane
Marietta, Georgia 30062

FEB - 8 2011

Re: K101902
Trade/Device Name: J tack
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: January 16, 2011
Received: January 18, 2011

Dear Ms. Cathy Cambria:

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

510(k) Number K101902

Device Name: J tack

Indication for use:

The J Tac is intended for use to fixate and stabilize bioresorbable and non-resorbable barrier membranes used for regeneration of tissue in the oral cavity or in dental situations that require membrane use or fixation.

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)

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

510(k) Number: K101902