K060691

1. 510(k) Summary

Submitter: A. Titan Instruments, Inc.

JUN 12 2006

Address: 97 Main St.
Hamburg, NY 14075
USA
Phone number: (716) 648-9272
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Contact person: Mr. Sebastian Czerny
Date prepared: 05/23/06
Trade name: Easy X-Trac System
Common name: Tooth Extraction System
Classification name: Forceps, Tooth Extractor, Surgical
Substantial equivalence claimed to:

1. Meisinger Benex, 872.4565 510(k) exempt

Description:
The Easy X-Trac System is a tooth extraction system that is used to extract single- and double-rooted teeth. Use of this system may minimize bone loss, reduce damage to soft tissue and preserve the alveolous prior to immediate or delayed implant placement more than with regular extraction instruments such as extraction forceps and root elevators.

Intended use:
The Easy X-Trac System is to be used to extract single and double rooted teeth as an implemented pre-implantological method by professionals only.

Summary of technological characteristics:
The Easy X-Trac System uses a complete vertical lifting motion without rotary- or tliting movements to lift a tooth out of the socket. By using this technique the user might have a greater chance of preserving the socket and preventing damage to hard soft tissues such as lamella and buccal and labial plates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2006

Mr. Michael Tuber
President
A Titan Instruments, Incorporated
97 Main Street
Hamburg, New York 14075

Re: K060691
Trade/Device Name: Easy X –Trac System
Regulation Number: 872.4565
Regulation Name: Dental Hand Instrument
Regulatory Class: I
Product Code: EMG
Dated: May 23, 2006
Received: May 24, 2006

Dear Mr. Tuber:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060691

4. Indications for Use

510(k) Number: None currently exists.

Device Name: Easy X-Trac System

Indications for Use:
The Easy X-Trac is only to be used for extraction of single and double rooted teeth by dental professionals only. The system may be used to extract broken-down teeth with limited access to the root or to extract vertically or horizontally fractured teeth.

Prescription Use ✓ AND/OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon
...on Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number: K060691