510(k) Summary

K100932

DEC 27 2010

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

A. SUBMITTER INFORMATION

Company Name:	Prismatik Dentalcraft, Inc.
Company Address:	4141 Mac Arthur Boulevard Newport Beach, CA 92660
Company Phone:	(949) 440-2683
Company FAX:	(949) 440-2787
Contact Person:	Keith D. Allred Kathleen Dragovich, (949) 399-1940
Date Summary Prepared:	December 13, 2010

B. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Inclusive® Mini Implant
21 CFR Reference:	872.3640
21 CFR Common Name:	Endosseous Dental Implant
Classification:	Class II
Panel:	Dental DZE

C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:	IMTEC Sendax MDI and MDI Plus, K031106 (8/12/2003)
Trade/Proprietary Name:	IMTEC MDI MII One-Piece Implant, 2.9mm, K08165 (9/19/2008)

D. DEVICE DESCRIPTION

Prismatik Dentalcraft, Inc.'s Inclusive® Mini Implant is a one-piece, root-form, screw-type, endosseous dental implant. These self-tapping, threaded implants are manufactured from Ti6Al-4V ELI, titanium alloy for surgical implant applications (ASTM F136). The Mini Implant will be available in 9 sizes: 2.2mm, 2.5mm, and 3.0mm diameters in 10mm, 13mm, and 15mm thread lengths. The implant body has a thread design for bone compression and the surface is blasted and etched to facilitate osseointegration. The 3.0mm implant has micro-threads at the intra-osseous collar to preserve crestal bone. The Mini Implants have a transgingival collar 2mm in height and an O-Ball design prosthetic head.

E. INDICATIONS FOR USE

Inclusive® Mini Implants are self-tapping threaded titanium screws indicated for long-term applications. Inclusive® Mini Implants may also be used for provisional applications. These devices will allow immediate loading and long-term stabilization of dentures and provisional

stabilization of dentures while standard implants heal. To be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

F. SUBSTANTIAL EQUIVALENCE

The Inclusive® Mini Implants are substantially equivalent to the IMTEC Sendax MDI and MDI Plus and the IMTEC MDI MII One-Piece Implant, 2.9mm. These devices are all one piece endosseous dental implants that are a combination of implant and abutment sections. All are made of titanium alloy commonly used for surgical implant applications. Also, the retention feature on the Inclusive® Mini Implant which retains the denture is identical to the predicate devices. The implants are intended for use in long-term and provisional applications. They all allow immediate loading and long-term stabilization of dentures and provisional stabilization of dentures while standard implants heal. All are provided STERILE.

Element of Comparison	Prismatik's Inclusive® Mini Implant	IMTEC Sendax MDI and MDI Plus	IMTEC MDI MII One-Piece Implant, 2.9mm
Material	Titanium Alloy	Titanium Alloy	Titanium Alloy
Diameters (mm)	2.2, 2.5, 3.0	1.8, 2.1, 2.4	2.9
Lengths (mm)	10, 13, 15	10, 13, 15, 18	10, 13, 15, 18
Prosthetic Head	O-Ball	O-Ball, Square	O-Ball, Square
Driver Connection	Square	Square	Square
Housing/O-Ring	Titanium Alloy/EPDM	Titanium Alloy/EPDM	Titanium Alloy/EPDM
Indications	Inclusive® Mini Implants are self-tapping threaded titanium screws indicated for long-term applications. Inclusive® Mini Implants may also be used for provisional applications. These devices will allow immediate loading and long-term stabilization of dentures and provisional stabilization of dentures while standard implants heal. To be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.	The MDI and MDI PLUS are self-tapping titanium threaded screws indicated for long-term intra-bony applications. Additionally, the MDI may also be used for inter-radicular transitional applications. These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full or partial endentulism, and employing minimally invasive surgical intervention.	The MII implant is intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. The MII implant is indicated for immediate loading when good primary stability is achieved. Additionally, this device will permit stability and long term fixation of upper and lower dentures in edentulous cases.
Sterility	STERILE	STERILE	STERILE

G. PERFORMANCE DATA

The Inclusive® Mini Implants were subjected to verification and validation studies. This testing was conducted in accordance with the FDA Guidance for Industry and FDA Staff, Class II Special Controls Guidance document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments issued May 12, 2004. The results of the testing demonstrate the Inclusive® Mini Implants are safe and effective for use.

Testing included Static and fatigue strength, sterilization validation, bioburden, and shelf life validation, packaging integrity, cytotoxicity, and independent clinician evaluations.

H. COMPARISON OF TECHNOLOGICAL DIFFERENCES

There are no known technological differences between the Inclusive® Mini Implants and those of the predicate devices.

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

Mr. Keith Allred
Director, Professional Services
Prismatik Dentalcraft, Incorporated
4141 Mac Arthur Boulevard
Newport Beach, California 92660

DEC 27 2010

Re: K100932
Trade/Device Name: Inclusive Mini Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 13, 2010
Received: December 14, 2010

Dear Mr. Allred:

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.

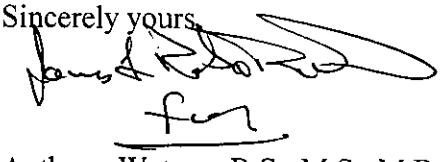
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony 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

PRISMATIK
DENTALCRAFT. INC

Prismatik Dentalcraft, Inc.
4141 Mac Arthur Boulevard
Newport Beach, CA 92660

INDICATIONS FOR USE STATEMENT

510(K) Number: K100932

DEC 2 7 2010

Device Name: Inclusive Mini Implant

Indications for Use:

Inclusive Mini Implants are self-tapping threaded titanium screws indicated for long-term applications. Inclusive Mini Implants may also be used for provisional applications. These devices will allow immediate loading and long-term stabilization of dentures and provisional stabilization of dentures while standard implants heal. To be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____ (Part 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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K100932