APR 0 5 2013

510(k) Summary
OCO Biomedical, Inc.
I Macro 6.0mm X 6.0mm
K122198

April 3, 2013

ADMINISTRATIVE INFORMATION

Manufacturer Name	OCO Biomedical, Inc. 9550 San Mateo Blvd. NE, Suite C Albuquerque, NM 87113 Telephone: +1 (505) 293-0025 Fax: +1 (505) 293-0447
Official Contact	David D. Dalise D.D.S. President/ Owner
Representative/Consultant	Linda K. Schulz Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: LSchulz@paxmed.com FLarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	I Macro 6.0mm X 6.0mm Implant
Common Name	Dental implant
Classification Name	Implant, endosseous, root form
Classification Regulation	Class II, 21 CFR 872.3640
Product Code	DZE
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

The I Macro 6.0mm X 6.0mm Implant system is intended for implantation in the maxillary or mandibular molar region where bone exists. This Macro implant provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or complete arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with proper occlusal loading, to restore the chewing function.

DEVICE DESCRIPTION

The I Macro 6.0mm X 6.0mm implants are self-tapping; commercially pure, CP Titanium or Titanium Alloy threaded screws, with light grit blasting or roughened surface treatment. These materials and procedures are exactly the same as cleared in the OCO Biomedical submission K110337. The I Macro 6.0mm X 6.0mm Implant is available in a 6.0mm diameter and a 6.0mm length.

EQUIVALENCE TO MARKETED DEVICE

OCO Biomedical, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the I Macro 6.0mm X 6.0mm Implants are substantially equivalent in indications and design principles to the following legally marketed predicate devices:

OCO Biomedical, I Macro Implant System, K110337
OCO Biomedical, TSI & ERI, K090174
"O" Company, Inc., Immediate Stabilizing Implant (ISI), K033392
"O" Company, Inc., OCO Dental Implant (5.0 mm Diameter), K023336
Implant Direct, LLC, Spectra Dental Implant System, K061319
Southern Implants, Inc., Endosseous Dental Implant System, K071161
Megagen Implant Company, LTD, Rescue External Implant System, K081302
Astra Tech AB, Astra Tech Implant System, K101732
Bicon, Inc., 6.0 x 5.7mm Dental Implant, K010185
Bicon, LLC, Bicon Implants with a 2.5mm Internal Connection, K092035
Bicon, LLC, The Bicon 5.0 x 5.0mm and 6.0 x 5.0mm Dental Implant, K073368
Bicon, Inc., The 5.0 x 6.0mm Dental Implant, K062044
Bicon, Inc., 4.5 x 6.0mm and 6.0 x 6.0mm Dental Implant, K050712
Bicon, Inc., The 5.0.x 6.0mm Dental Implant, K042637

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: engineering analysis, dimensional analysis, pull-out testing, and static and dynamic compression-bending testing according to ISO 14801.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. They encompass the same range of physical dimensions, including diameter and length of the implants. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Overall, I Macro 6 x 6 has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

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

April 5, 2013

OCO Biomedical, Incorporated
C/O Ms. Linda K. Schulz
PaxMed International, Limited Liability Company
11234 El Camino Real, Suite 200
SAN DIEGO CA 92130

Re: K122198
Trade/Device Name: I Macro 6.0mm x 6.0mm
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 15, 2013
Received: March 18, 2013

Dear Ms. Schulz:

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 -S FDA for

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

Indications for Use

510(k) Number: K122198

Device Name: I Macro 6.0mm x 6.0mm

Indications for Use:

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Susan Runner, DDS, MA

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

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