IMPLADENT LTD.
198-45 Foothill Avenue, Holliswood NY 11423

Advancing the Science of Implantology
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K090794

510(K) SUMMARY

Type of Submission:	Traditional Premarket Notification 510(k) 21 CFR 807.92 March 19, 2009
	DEC 10 2009
Submitted by:	Impladent Ltd. 198-45 Foothill Avenue Holliswood NY 11423-1611
Contact Person:	Maurice Valen President; Director of R&D Phone: 718 465-1810 Fax: 718 464-9620 Email: maurice@impladentltd.com or ginnyv@earthlink.net
Establishment Registration:	2431866
Common Name:	Bone Graft Material
Proprietary Name:	OsteoTape®
Classification:	Class II
Classification Regulation:	21 CFR 872.3930
Product Code:	LYC - Bone Grafting Material, Synthetic
Review Panel:	Dental
Confidentiality:	Under section 21 CFR 807.95, selected pages and/or sections have been marked as "CONFIDENTIAL"; any request for same under Freedom of Information Act should be purged.
Purpose of Submission:	Evidence herein is submitted to establish substantial equivalence for the product OsteoTape® to devices marketed in interstate commerce prior to May 28, 1976, and to legally marketed predicate devices cleared via the 510(k) process.
Performance Standards:	No performance standards have been established under Section 514
Special Controls:	Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices

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DEVICE DESCRIPTION

OsteoTape®, an OsteoGen® Collagen Resorbable Bone Graft Matrix (OsteoTape) in various preformed shapes, is a resorbable bone grafting substitute comprised of highly purified Type I bovine collagen, used as a carrier derived from bovine Achilles tendon, combined with crystals of the product OsteoGen®, a synthetic bioactive resorbable graft of the non-ceramic hydroxylapatite category. The product is supplied in cubes and strip forms, sterile, and for single use only.

INDICATIONS FOR USE

OsteoTape®, an OsteoGen® Collagen Resorbable Bone Graft Matrix (OsteoTape), is indicated for periodontal and maxillofacial use in surgical procedures, to be placed in sockets for the insertion of dental implants after healing; for the containment of bone graft granules after tooth extraction; repair of periodontal infrabony defects and ridge preservation; buccal onlay grafting in conjunction with OsteoTape® granules and/or strips; to augment the sinus; and, for guided bone regeneration (GBR) techniques. The non-ceramic material can also be used for wound healing post-dental implant surgery and over titanium implant devices if primary closure is not attainable for guided tissue regeneration (GTR). Titanium tack-screws may be used to immobilize OsteoTape®.

CONFORMANCE WITH PERFORMANCE STANDARDS

Voluntary standards to which OsteoTape®, an OsteoGen® Collagen Resorbable Bone Graft Matrix, complies include:

ASTM F2212-08e1	Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)
ASTM F1185-03	Standard Specification for Composition of Hydroxylapatite for Surgical Implants
ANSI/AAMI/ ISO 11137	Sterilization of Health Care Products- Radiation Sterilization
AAMI TIR 27	Sterilization of Health Care Products - Radiation Sterilization- Substantiation of 25kGy as a sterilization dose - Method VD_{max}

For Sterilization and Biocompatibility standards used, please refer to Sections 14 and 15.

SPECIAL CONTROLS

A Special Control that applies to OsteoTape®, an OsteoGen® Collagen Resorbable Bone Graft Matrix, is the Guidance for Industry and FDA Staff: Class II Special Control Guidance Document: Dental Bone Grafting Materials, issued on April 28, 2005.

SUMMARY/COMPARISON OF TECHNICAL CHARACTERISTICS

OsteoTape®, an OsteoGen® Collagen Resorbable Bone Graft Matrix, and its predicate devices have the same technology characteristics according to specified standards. In particular, OsteoTape® and its predicate devices are similar with respect to intended use, material application, structure, material composition, characterization and similar sizes.

SAFETY

OsteoTape®, an OsteoGen® Collagen Resorbable Bone Graft Matrix, has been evaluated as to its safety and effectiveness by a number of standardized tests to assess its safety, viral inactivation, and biocompatibility *in vivo* and *in vitro,* and is confirmed in the medical literature as being safe and effective for a variety of dental applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Maurice Valen
President
Director of R&D
Impladent, Limited
198-45 Foothill Avenue
Holliswood, New York 11423-1611

DEC 10 2009

Re: K090794
Trade/Device Name: OsteoTape™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Codes: NPM
Dated: December 2, 2009
Received: December 3, 2009

Dear Mr. Valen:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K090794**

Device Name: **OsteoTape®**

Indications for Use:

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Prescription Use **YES** AND/OR Over-the-Counter **NO**
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mary for MSR

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

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