K120792

SEP 5 2012

5. 510(K) SUMMARY

Submission Correspondent

Company Name:	Emergo Group, Inc.
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Submission Date:	March 8, 2012
Website:	www.emergogroup.com

Submission Sponsor

Company Name:	Leader Italia, Srl
Company Address:	Via Aquileja 43/B Cinisello Balsamo (MI) 20092
Country:	Italy
Phone:	39 02 618651
Fax:	39 02 61290676
Website:	www.leaderitalia.it

Device Classification

Device Sponsor:	Leader Italia, Srl
Device Trade Name:	TiXos Implant System (dental implants)
Product Classification Name:	Implant, Endosseous, Root-Form
Product Code:	DZE
Regulation Number:	872.3640
Classification Panel:	Dental Devices
Regulatory Class:	Class 2

Predicate Device

IMPLUS Implant System (K062931) manufactured by Leader Italia, Srl

Indications for Use

TiXos dental implants are permanent devices for single use only that are intended to be surgically placed in the bone of the mandibular and/or maxillary dental arches of the patient in order to restore their original dental function and aesthetic features by providing support for fixed and/or removal prosthesis. TiXos dental implants can support single tooth, multiple tooth, or total prosthesis restorations and are compatible with the following dental abutments manufactured by Leader Italia that were previously cleared under K062931.

ABUTMENT CODE	ABUTMENT NAME
Tixos Internal Hex Ø 3.3 Platform Size (mm): 3.5	
01ATI33	Straight Abutment Ø 4.5
01ATIF33	Frictioning Abutment Ø 4.5
01AS33	Shoulder Abutment Ø 4.5
01ASF33	Shoulder Frictioning Abutment Ø 4.5
01AP1533	15° Angled Abutment Ø 4.5
01AP601533	15° Angled Abutment Ø 6
01AP15F33	15° Angled Frictioning Abutment Ø 4.5
01AP2533	25° Angled Abutment Ø 4.5
01AP602533	25° Angled Abutment Ø 6
01AP25F33	25° Angled Frictioning Abutment Ø 4.5
01AB332, 01AB333 01AB334, 01AB335	Ball Abutment Ø 4.5
01ABA332, 01ABA333 01ABA334, 01ABA335	Ball Abutment with Antirotation Base Ø 4.5
01ATS331, 01ATS332	Tissue Abutment Ø 4.5 for Screw-Retained Denture
01AATI331A, 01AATI332A	Antirotation Abutment
Tixos Internal Hex Ø 3.75 Platform Size (mm): 4	
01ATIC4	Straight Abutment Ø 4.5
01ATIC6	Straight Abutment Ø 6

ABUTMENT CODE	ABUTMENT NAME
Tixos Internal Hex Ø 4.5 Platform Size (mm): 5	
01ATI5	Straight Abutment Ø 5
01ATIF5	Frictioning Abutment Ø 5
01AP1560	15° Angled Abutment Ø 6
01AB502, 01AB503 01AB504	Ball Abutment Ø 5
01AATI451A	Antirotation Abutment
01ATI5	Straight Abutment Ø 5
Tixos Internal Hex Ø 5.5 Platform Size (mm): 6	
01AB602, 01AB603 01AB604	Ball Abutment Ø 6
01ATI6055	Straight Abutment Ø 6
01ATI60F55	Frictioning Abutment Ø 6
01AATI551A	Antirotation Abutment
Tixos External Hex Ø 3.3/3.75 Platform Size (mm): 4.1	
01ATIX33	Straight Abutment Ø 4.5
01ATI60X33	Straight Abutment Ø 6
01ATIXF33	Straight Frictioning Abutment Ø 4.5
01AXS33	Shoulder Abutment Ø 4.5
01AXS6033	Shoulder Abutment Ø 6
01AXSF33	Shoulder Frictioning Abutment Ø 4.5

01ATICF4	Frictioning Abutment Ø 4.5
01ASC4	Shoulder Abutment Ø 4.5
01ASC6	Shoulder Abutment Ø 6
01ASCF4	Shoulder Frictioning Abutment Ø 4.5
01APC1540	15° Angled Abutment Ø 4.5
01APC601540	15° Angled Abutment Ø 6
01APC2540	25° Angled Abutment Ø 4.5
01APC602540	25° Angled Abutment Ø 6
01APC15F40	15° Angled Frictioning Abutment Ø 4.5
01APC25F40	25° Angled Frictioning Abutment Ø 4.5
01ATIM4	Multi-function Abutment
01ABC452, 01ABC453 01ABC454, 01ABC455	Ball Abutment Ø 4.5
01ABA402, 01ABA403 01ABA404, 01ABA405	Ball Abutment with Antirotation Base Ø 4.5
01AC1A, 01AC2A	Antirotation Abutment

01APX1533	15° Angled Abutment Ø 4.5
01APX2533	25° Angled Abutment Ø 4.5
01ABX332, 01ABX333 01ABX334, 01ABX335	Ball Abutment Ø 4.5
01ABXA2, 01ABXA3 01ABXA4, 01ABXA5	Ball Abutment with Antirotation Base
01AATIX331A, 01AATIX332A	Antirotation Abutment
Tixos External Hex Ø 5	**Platform Size (mm): 4.1**
01AATIX501A	Antirotation Abutment
01ATIX5	Straight Abutment Ø 5
01ATIXF5	Straight Frictioning Abutment Ø 5

Device Description

Leader Italia's line of TiXos dental implants are titanium endosseous implants that are fabricated by a process called Direct Laser Metal Forming ("DLMF"). This fabrication process results in the production of an implant with a porous surface characterized by open intercommunicating cavities and networks. The implants are intended to be surgically placed in the bone of the mandibular and/or maxillary dental arches of the patient to provide support for their fixed and/or removal prosthesis, and to restore their original aesthetic features, dental and/or masticatory function. TiXos dental implants are permanent dental devices for single use and can support single tooth, multiple tooth, or total prosthesis restorations. These implants have been designed to be used exclusively with Leader Italia's line of prosthetic abutments and surgical instruments. TiXos dental implants are gamma sterilized, have a five year shelf-life, and are offered in two basic model configurations called *Cylindrical* and *S-Type*, and a number of different sizes and diameters as shown below.

TiXos Implants Models & Sizes	
TiXos Cylindrical Line	
Internal Connection	Ø 3.3 mm / L 8, 10, 11.5, 13, 16 mm Ø 3.75 mm / L 8, 10, 11.5, 13, 16 mm Ø 4.5 mm / L 8, 10, 11.5, 13, 16 mm Ø 5.5 mm / L 8, 10, 11.5, 13 mm
External Connection - Long	Ø 3.3 mm / L 10, 11.5, 13, 16 mm Ø 3.75 mm / L 8, 10, 11.5, 13, 16 mm Ø 5.0 mm / L 8, 10, 11.5, 13 mm
TiXos S-Type Line	
S-Type	Ø 3.75 mm / L 10, 11.5, 13 mm Ø 4.5 mm / L 10, 11.5, 13 mm

Predicate Device Comparison

Aside from the slight differences in sizes (i.e., diameter and length) between TiXos and the predicate implants, TiXos implants are manufactured using Leader Italia's Direct Laser Metal Forming process as opposed to the more conventional machining and acid etching techniques the company uses to produce its IMPLUS implants.

Both TiXos and IMPLUS implants are single use, permanent dental devices that are surgically placed in either the mandibular and/or maxillary dental arches of the patient; both implants are cleaned, packaged and gamma sterilized in identical manners; use the same abutments that have been designed and manufactured by Leader Italia, and have identical implant-to-abutment interface connections; and can be implanted using the same surgical instruments.

Some select properties and characteristics of the subject and predicate devices are compared side-by-side as shown below.

Substantial Equivalence Comparison Selected Properties Of IMPLUS vs. TiXos Dental Implants		
Feature	Leader Italia IMPLUS Implants	Leader Italia TiXos Implants
510(k):	K062931	Pending
Product Code:	DZE	DZE
Regulation Number:	872.3640	872.3640
Regulation Name:	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Implant Material:	Ti grade 4	Ti-6Al-V4
Raw Material Form:	Rod Stock	Powder
Implant Fabrication Method:	Traditional CNC Machining	Direct Laser Metal Forming
Surface Formed By:	Acid Etching	Direct Laser Metal Forming
Implant Geometries:	Various	Various
Designed For Prosthetic Abutments:	Yes	Yes
Implant/abutment Interface:	Internal and External	Internal, External, and Integrated Abutment
Implant Diameters (mm):	3.3, 3.75, 4.5, 4.75, 5.0 5.5, 5.75, 6	3.3, 3.75, 4.5, 5.0, 5.5
Implant Lengths (mm):	8, 10, 11.5, 13, 16, 20	8, 10, 11.5, 13, 16
Single Use:	Yes	Yes
Sterile:	Yes	Yes
Intended Use:	Titanium endosseous implants to be surgically placed in the bone of the mandibular and/or maxillary dental arches in order to provide support for fixed	Titanium endosseous implants to be surgically placed in the bone of the mandibular and/or maxillary dental arches in order to provide support for fixed

	and/or removal prosthesis to restore the original aesthetic features, dental and/or masticatory function to the patient after osseointegration has taken place.	and/or removal prosthesis to restore the original aesthetic features, dental and/or masticatory function to the patient after osseointegration has taken place.

Non-Clinical Data – Bench Testing & Device Validations

As part of demonstrating the safety and effectiveness of TiXos dental implants and in showing substantial equivalence to its IMPLUS implants, Leader Italia submitted a number of its dental implants for fatigue testing in accordance with ISO 14801, *Dentistry – Implants – Dynamic Fatigue Test for Endosseous Dental Implants*, where their implants were tested in dry (i.e., air) environment. Testing was performed on the TiXos dental implants to simulate *worst-case* loading conditions and was compared to the predicate device and found it be similar.

Further, TiXos dental implants also underwent extensive validation activities for biocompatibility, cleaning, packaging, shelf-life and sterilization in accordance with *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*, and all applicable recognized FDA consensus standards for dental implants, including but not limited to, ISO 10993-5, *Biological Evaluation of Medical Devices – Part 5: Test for in vitro Cytotoxicity*.

Clinical Data

As part of demonstrating the safety and effectiveness of its TiXos dental implants, Leader Italia submitted a prospective summary report, and radiographic images, to the FDA that were part of its European clinical study and represent follow-up data for their implants at different time intervals after the implants were loaded with their prosthetic abutments. Results of this clinical information have been published in a number of peer reviewed scientific dental journals as shown below.

TiXos Implants Summary of In-Vivo Clinical Articles	
Title	**Publication**
Early Human Bone Response to Laser Metal Sintering Surface Topography: A Histological Report	*Journal of Oral Implantology* Vol. XXXVI/No. Two, 2010
Influence of Direct Laser Fabrication Implant Topography on Type IV Bone: A Histomorphometric Study In Humans	*Journal of Biomedical Materials Research*, Part A, 9 July, 2009
SEM and X-Ray Dispersive Spectrometry Evaluation of Direct Laser Metal Sintering Surface and Human Bone Interface: A Case Series	*Lasers In Medical Science*, 2011
Single-Tooth Direct Laser Metal Forming (Dlmf) Titanium Implants: Results From A 1- Year Prospective Multicenter Study	*Lasers in Medical Science*
Report on a Screw on Sintered Titanium, Removed After Two Months of Osseointegration	*The University of Insubria, Varese, Italy* - Department of Human Morphology, 2008

Prospective Clinical Evaluation of 201 Direct Laser Metal Forming Implants: Results From a 1 Year Multicenter Study	*Lasers in Medical Science*, accepted on February 2011
Dental implants from laser fusion of titanium microparticles: from research to clinical applications	*Journal of Osseointegration*
Immediate Loading of Mandibular Overdentures Supported by Unsplinted Direct Laser Metal-Forming Implants: Results From a 1-Year Prospective Study	*Journal of Periodontol*

Substantially Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the new device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the TiXos and IMPLUS dental implants do not raise any questions regarding its safety and effectiveness. Leader Italia's TiXos Implant System, as designed and manufactured, is therefore determined to be substantially equivalent to their IMPLUS Implant System previously cleared under K062931.

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

Leader Italia S.R.L.
C/O Mr. Stuart R. Goldman
Senior Consultant
Emergo Group, Incorporated
611 West 5TH Street, Third Floor
Austin, Texas 78701

SEP 5 2012

Re: K120792
Trade/Device Name: TiXos Implant System (Dental Implants)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 1, 2012
Received: August 3, 2012

Dear Mr. Goldman:

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.

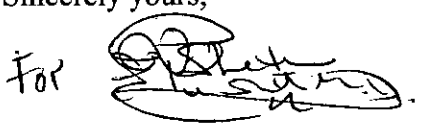
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

INDICATIONS FOR USE

510(k) Number (if known): 120792

TiXos dental implants are permanent devices for single use only that are intended to be surgically placed in the bone of the mandibular and/or maxillary dental arches of the patient in order to restore their original dental function and aesthetic features by providing support for fixed and/or removal prosthesis. TiXos dental implants can support single tooth, multiple tooth, or total prosthesis restorations and are compatible with the following dental abutments manufactured by Leader Italia that were previously cleared under K062931.

ABUTMENT CODE	ABUTMENT NAME
Tixos Internal Hex Ø 3.3 Platform Size (mm): 3.5	
01ATI33	Straight Abutment Ø 4.5
01ATIF33	Frictioning Abutment Ø 4.5
01AS33	Shoulder Abutment Ø 4.5
01ASF33	Shoulder Frictioning Abutment Ø 4.5
01AP1533	15° Angled Abutment Ø 4.5
01AP601533	15° Angled Abutment Ø 6
01AP15F33	15° Angled Frictioning Abutment Ø 4.5
01AP2533	25° Angled Abutment Ø 4.5
01AP602533	25° Angled Abutment Ø 6
01AP25F33	25° Angled Frictioning Abutment Ø 4.5
01AB332, 01AB333 01AB334, 01AB335	Ball Abutment Ø 4.5
01ABA332, 01ABA333 01ABA334, 01ABA335	Ball Abutment with Antirotation Base Ø 4.5
01ATS331, 01ATS332	Tissue Abutment Ø 4.5 for Screw-Retained Denture
01AATI331A, 01AATI332A	Antirotation Abutment
Tixos Internal Hex Ø 3.75 Platform Size (mm): 4	
01ATIC4	Straight Abutment Ø 4.5
01ATIC6	Straight Abutment Ø 6
01ATICF4	Frictioning Abutment Ø 4.5
01ASC4	Shoulder Abutment Ø 4.5
01ASC6	Shoulder Abutment Ø 6
01ASCF4	Shoulder Frictioning Abutment Ø 4.5
01APC1540	15° Angled Abutment Ø 4.5
01APC601540	15° Angled Abutment Ø 6
01APC2540	25° Angled Abutment Ø 4.5
01APC602540	25° Angled Abutment Ø 6
01APC15F40	15° Angled Frictioning Abutment Ø 4.5
01APC25F40	25° Angled Frictioning Abutment Ø 4.5
01ATIM4	Multi-function Abutment
01ABC452, 01ABC453 01ABC454, 01ABC455	Ball Abutment Ø 4.5
01ABA402, 01ABA403 01ABA404, 01ABA405	Ball Abutment with Antirotation Base Ø 4.5
01AC1A, 01AC2A	Antirotation Abutment

ABUTMENT CODE	ABUTMENT NAME
Tixos Internal Hex Ø 4.5 Platform Size (mm): 5	
01ATI5	Straight Abutment Ø 5
01ATIF5	Frictioning Abutment Ø 5
01AP1560	15° Angled Abutment Ø 6
01AB502, 01AB503 01AB504	Ball Abutment Ø 5
01AATI451A	Antirotation Abutment
01ATI5	Straight Abutment Ø 5
Tixos Internal Hex Ø 5.5 Platform Size (mm): 6	
01AB602, 01AB603 01AB604	Ball Abutment Ø 6
01ATI6055	Straight Abutment Ø 6
01ATI60F55	Frictioning Abutment Ø 6
01AATI551A	Antirotation Abutment
Tixos External Hex Ø 3.3/3.75 Platform Size (mm): 4.1	
01ATIX33	Straight Abutment Ø 4.5
01ATI60X33	Straight Abutment Ø 6
01ATIXF33	Straight Frictioning Abutment Ø 4.5
01AXS33	Shoulder Abutment Ø 4.5
01AXS6033	Shoulder Abutment Ø 6
01AXSF33	Shoulder Frictioning Abutment Ø 4.5
01APX1533	15° Angled Abutment Ø 4.5
01APX2533	25° Angled Abutment Ø 4.5
01ABX332, 01ABX333 01ABX334, 01ABX335	Ball Abutment Ø 4.5
01ABXA2, 01ABXA3 01ABXA4, 01ABXA5	Ball Abutment with Antirotation Base
01AATIX331A, 01AATIX332A	Antirotation Abutment
Tixos External Hex Ø 5 Platform Size (mm): 4.1	
01AATIX501A	Antirotation Abutment
01ATIX5	Straight Abutment Ø 5
01ATIXF5	Straight Frictioning Abutment Ø 5

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

510(k) Number: K120792

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)