



K06 2931

510(k) Summary (21 CFR 807.92)
LEADER ITALIA IMPLANTS

I General Information

Submitter: LEADER ITALIA S.r.l.
Via Aquileja, 49
Cinisello Balsamo (MILANO) ITALY

Telephone: +39 02 618651 – Company Number
+39 02 61865368 – Contact Person

Fax: +39 02 61290676

Contact Person: Mariaelena Costantin
Export Manager

Summary Preparation Date: March 22nd, 2007

NOV 28 2007

II Names

Device Name: IMPLUS
Endosseous Dental Implant

Primary Classification Name: DZE – Implant, Endosseous, Root-Form

III Predicate Devices

- Sulzer Dental Screw-Vent Dental Implant System (K011028) vs IMPLUS
- Branemark Integration Endosseous Implant (K021355) vs IMPLUS

IV Product Description

Leader Italia IMPLUS implants are available in cylindrical or tapered shape, with different dimensions; connection to abutments is made by internal or external hexagon.
All implants are manufactured from medical titanium in grade 4 (Ref. ASTM F67) with a modified surface for optimum osseointegration.



The implants are all provided sterile in a packaging complete with mount transfer.

IMPLUS Implants List:

SHAPE	HEXAGON	DIAMETER	LENGTH
Cylindrical	Internal	3,3 mm	8-10-11,5-13-16 mm
Cylindrical	Internal	3,75 mm	8-10-11,5-13-16 mm
Cylindrical	Internal	4,5 mm	8-10-11,5-13-16 mm
Cylindrical	Internal	5,5 mm	8-10-11,5-13 mm
Cylindrical	External	3,3 mm	10-11,5-13-15 mm
Cylindrical	External	3,75 mm	8-10-11,5-13-15-18-20 mm
Cylindrical	External	5 mm	8-10-11,5-13 mm
Tapered	Internal	4 mm	8-10-11,5-13-16 mm
Tapered	Internal	5 mm	8-10-11,5-13-16 mm
Tapered	Internal	6 mm	8-10-11,5-13 mm
Tapered	External	4 mm	8-10-11,5-13-15 mm
Tapered	External	5 mm	8-10-11,5-13 mm

V Indications for Use

IMPLUS implant fixtures are intended 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 prosthetic in order to restore original features and masticatory functions. Implus implant fixtures are foreseen for permanent use. These fixtures are disposable and are for one-time use only. These fixtures are not to be re-cleaned or re-sterilized.

Leader Italia Implus implants can support a single tooth, more dental elements or total prosthesis.

If we loose a tooth, we can replace it without damaging the two close teeth when building the so called traditional “bridge”. The use of the implant allows us to obtain an optimal aesthetic and functional result. In fact, once the implant has been inserted in the bone, it rapidly becomes an integral part of it and it will become the artificial root on which the artificial tooth will be fastened.

If the missing teeth are more than one, the use of multiple implants allows us a sufficient number of artificial roots on which to fasten the necessary artificial teeth to complete the dental arch. In this way, the use of removable prosthesis with metal base (the so – called “plate”) is avoided as well as the use of healthy teeth as abutment for a bridge. In this



situation, the obtained results offers more comfort for the patient together with aesthetics and functionality and less reduction of tooth structure.

The choice of the implants is recommended also in case of total teeth absence on one or both of the dental arches. According to circumstances the dentist will consider how many implants should be inserted in the bone and whether to use a fixed or a movable prosthesis. In both cases, the prosthesis on implants have complete stability in all functions – such as speaking, smiling, chewing - and reduce the precarious stability problems that can be found in the traditional total prosthesis.

VI Safety and Effectiveness Information

Leader Italia implants have been manufactured and marketed in several countries (Italy, India, Poland Spain, Philippines, Estonia, Lithuania and more others) for years, and our customers found them to be safe and effective products, substantially equivalent to similar devices manufactured by competitors .

Biocompatibility: Implus Implants are made of Medical Titanium grade 4 (ASTM F67), abutments are made of Titanium grade 5 (ASTM F136-96).

This material is commonly used by manufacturer of dental implants following the widely recommended as the most suitable raw materials for contact with human tissue.

Leader's implants were also tested and found to be not cytotoxic according to standard UNI EN ISO 30993 part 5 of September 2000 by "BIOLAB" laboratory, Vimodrone, Milano, Italy (report n° SAM1282 dated 11th February 2003)

Mechanical and fatigue tests performed by "Politecnico di Milano" – Structural Engineering Department – demonstrated stiffness and durability of Leader Italia implants and abutments.

The tests were performed on IMPLUS implants diam.4 with 25° angled abutment (report 01/014/rel of 17th December 2001); test method is detailed in Section 18 pages 2, 3, 5 and 6.

Performance test and biological analysis demonstrated effectiveness of the sterilization procedure with gamma rays (report by BIOSTER laboratory issued on January 1998) and the packaging duration (5 years) according to results of report issued by BIOSTER on October 2003.

Additional information:

Following the start-up of the new production plant and clean room, new tests for validation of the sterilization procedure and of the packaging duration were performed (Report by BIOSTER laboratory issued on February 2nd 2007 and December 2006 respectively).

In accordance with standard ISO 14801 issued on 2003, laboratory tests were requested to Politecnico di Milano. Further Fatigue Tests are presently running according to standard ISO 14801; final results are foreseen next April 2007



VII Conclusion

Based on comparison to the predicate devices, we conclude that the products are substantially equivalent to currently marketed devices under the Federal Food, Drug and Cosmetic Act and presents no concerns about safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 28 2007

LEADER Italia S.r.l.
C/O Mr. Henry J. Vogelstein
Consultant
1349 Lexington Avenue
New York, New York 10128

Re: K062931
Trade/Device Name: IMPLUS
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 19, 2007
Received: October 22, 2007

Dear Mr. Vogelstein:

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



Indications for Use

510(k) Number (if known): K062931

Device Name: **IMPLUS**

Indications for Use:

IMPLUS implant fixtures are intended 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 prosthetics in order to restore original features and masticatory functions.

Implus implant fixtures are indicated for permanent use.

Implus implant fixtures are disposable and are for one-time use only. These fixtures are not to be re-cleaned or re-sterilized.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

Ken Mulvey for MSR

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

510(k) Number: K062931