FEB 2 7 2006

SUMMARY

Submitter's name: Leone S.p.A.
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Name of contact person: Greg Holland
Regulatory Specialists, Inc
3722 Ave. Sausalito
Irvine, CA 92606
Phone: 949-262-0411

Date the summary was prepared: March 3, 2005

Name of the device: Leone Implant System
Trade or proprietary name: Dental Implant
Common or usual name: Dental Implant
Classification name: Dental Implant

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Reference #	**Device Name**	**Manufacturer**
K994037	Bicon Dental Implant System	Bicon, Inc
K031055	ITI Dental Implant System	Straumann USA

Description of the device:

The Leone implant system is composed of a fixture and an abutment joined together by a self locking tapered connection due to a Morse cone and a hexagon. The prosthesis is then placed over the abutment.

Intended Use:

The Leone Implant System is indicated for single or multiple tooth

replacement, or for use in terminal or intermediate edentulous sites in the mandible and/or the maxilla, and for totally edentulous arches. The system is designed to be surgically inserted in the bone structure of the mouth in order to replace missing teeth. It can work as an abutment system for partial/total prosthetic restorations or as an anchorage system for removable prosthodontics.

Summary of the technological characteristics of our device compared to the predicate device:

Feature	Leone System	Bicon K994037	Straumann K031055
Intended Use	Designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridge work, partial dentures, and / or a single tooth replacement.	Designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal or intermediate abutment for fixed bridge work, partial dentures, and / or single tooth replacement.	Intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients. The ITI Dental Implants are for single-stage or two-stage surgical procedures.
Material	Titanium	Titanium	Titanium
Biocompatibility	Biocompatible	Biocompatible	Biocompatible

Conclusion

Based on the Intended Use, Materials and Biocompatibility, and when it is used, the Leone Implant System is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. The Leone Implant System raises no new issues of safety or effectiveness. Therefore, safety and effectiveness are reasonably assured, and substantial equivalence is supported, justifying 510(k) clearance of the Leone Implant System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2006

Leone SpA
C/O Mr. Greg Holland
Regulatory Specialists, Incorporated
3722 Avenue Sausalito
Irvine, California 92606

Re: K050586
Trade/Device Name: Leone Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: February 14, 2006
Received: February 15, 2006

Dear Mr. Holland:

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,

Susan Runner

for 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 Statement

510(k) Number (if known): K050586

Device Name: Leone Implant System

Indications For Use:

The Leone Implant System is indicated for single or multiple tooth replacement, or for use in terminal or intermediate edentulous sites in the mandible and/or the maxilla, and for totally edentulous arches. The system is designed to be surgically inserted in the bone structure of the mouth in order to replace missing teeth. It can work as an abutment system for partial/total prosthetic restorations or as an anchorage system for removable prosthodontics.

Prescription Use √ OR
(Per 21 CFR 801.109)

Over-The-Counter Use_____
(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

[illegible] General Hospital,
[illegible] Devices

K050586