

Submitter: Mario Gersberg, Pres. Odontit S.A. Buenos Aires, Argentina,
Phone: + 5411-4825-0221.

- I. **Classification Name and Number:** Endosseous Implant (DZE)
- II. **Common/Usual Name:** Mini-implants
- III. **Proprietary Name:** J.J.G. Evolution™ Mini-Implant System.
- IV. **Registration No.:** 9680963
- V. **Compliance with Performance Standards:** No performance standards are applicable, however we followed "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" issued May 12, 2004. The CP titanium used in these implants meets ASTM F - 67 "Specification for Unalloyed Titanium for Surgical Implant Applications," and the titanium alloy meets ASTM F - 136, "Standard Specifications for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical implant Applications."
- VI. **Description of the Device:** This device is an endosseous dental implant consisting of the major component, a root-form, screw type, self-tapping implant, and accessories, designed to facilitate placing and using the implant in various procedures. The accessories contact tissue for less than 1 hour and therefore are exempt from 510(k) requirements and are described only generally but are of course subject to general controls and are covered by the Quality System documents. The head of the implant has an internal square for insertion of the screw driver. The body has a cylindrical shape with tapered point with self tapping threads. The heads of this implant are provided in several shapes to meet several needs described in the indications section, including round, square, and cylindrical. The JJG Evolution™ implant is made of titanium or titanium alloy, both of which meet FDA recognized consensus standards.
- VII. **Labels and Labeling:** Draft labels of the JJG Evolution™ Mini-Implant system and instructions for use are provided.
- VIII. **Substantial Equivalence:** The JJG Evolution™ Mini-Implant system is substantially equivalent to several small implant systems currently on the market. Some of these are: Dentatus MTI Modular Transitional Implants cleared in K980620, MTI-MP Transitional Implants, cleared by Dentatus USA in K961704, Sendax MDI cleared by Sendax MDIC Management in K972351, the Bicortical Screw, cleared by Oraltronics in K983120, and

3i Std Threaded/Self Tapping, Threaded/3i Miniplant Implants, cleared by Implant Innovations, Inc., in K960417,

JJG Evolution™ Mini-Implant system implants are substantially equivalent to the Dentatus MTI implants in that they are manufactured from either titanium or titanium alloy. Like the Dentatus and Sendax implants (K980620, K972351) the JJG Evolution™ Mini-Implants are also one-piece, self-tapping and feature various head-types. They have diameters ranging from 1.5 to 2.8 in diameter (less than the more typical endosseous implants commonly used with abutments) and range in length from 10 to 20 mm while the Sendax implants range from 14 to 22 mm (overall) and the Dentatus implant are 14 to 2 mm. in length (including the head portion).

The JJG Evolution™ Mini-Implants are also substantially equivalent to several other endosseous implants cleared in 510(k)s but differ somewhat in use from regular endosseous implants. Like the Sendax implants, JJG implants may be used for transitional or long-term implantation to support prosthetics (single tooth, crown or bridge cases) to provide for mastication. If four are placed in the front maxilla and splinted together, they may be loaded immediately.

The implant is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use as predicate devices, intended to provide These devices are intended for intra-bony and inter-radicular transitional applications, to permit immediate splinting stability and ongoing fixation of new or existing crown and bridge installations for full or partial edentualism such as:

Support anchors for temporary restorations during the healing and osseointegration process of permanent implants; Immediate loading temporary abutments for repairing failing tooth and implant supported restorations; Transitional supports for immediate replacement of missing teeth; and for use in front maxilla where 4 or more implants are splinted together, may be loaded immediately.

2. The technological characteristics for this product are similar (nearly identical) to those of the predicate devices and those currently on the market They are screw-type, self-tapping endosseous dental implants with design and manufacturing concepts and materials similar to those of the predicate devices.

K072917

XII

510(k) SUMMARY

Submitter: Mario Gersberg, Odontit S.A., Buenos Aires Argentina, Phone:
+5411-4825-0221.

- I. **Classification Name and Number:** Orthodontic endosseous Implant (DZE) and (OAT).
- II. **Common/Usual Name:** Orthodontic implant
- III. **Proprietary Name:** JJG Evolution™ Orthodontic Implant System
- IV. **Registration No.:** 9680963
- V. **Compliance with Performance Standards:** No performance standards are applicable, however we followed "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" issued May 12, 2004. The CP titanium used in these implants meets ASTM F - 67 "Specification for Unalloyed Titanium for Surgical Implant Applications," and the Titanium Alloy meets ASTM F - 136, "Standard Specifications for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical implant Applications.
- VI. **Description of the Device:** This device is an endosseous dental implant consisting of the major component, a root-form, screw type implant with a specialized head, and accessories, designed to facilitate placing and using the implant in orthodontic procedures.. The accessories contact tissue for less than 1 hour and therefore are exempt from 510(k) requirements and are described only generally but are described in Quality System documentation.. The smoothly curved head has a groove in the middle for the attachment of elastics, chains, or coil springs commonly used in orthodontics. The head has a 0.7 mm aperture where a wire or auxiliary can be attached. The rounded head of the implant has an internal square for insertion of the screw driver. The body has a cylindrical shape with tapered point with self tapping threads. The JJG Evolution™ Orthodontic implant is made of titanium or titanium alloy, both of which meet FDA recognized consensus standards.
- VII. **Labels and Labeling:** Draft labels of the JJG Evolution™ system and instructions for use are provided.
- VIII. **Substantial Equivalence:** The JJG Evolution™ system is substantially equivalent to several small implant systems currently on the market. Some of these are: K063770 by Alpha-Bio Tec, K062733 by Dentaurum, K062367 by the Micerium Group, K062156 by Osstem Implant Co., K060062 by Institut Straumann, K050568 by Ortholution Co., K042965 by Dentarum,

Inc., and K031936 by Osteomed. The implant is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The “510(k) “Substantial Equivalence” Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use as predicate devices, intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth.
2. The technological characteristics for this product are similar to those of the predicate devices and those currently on the market. They are screw-type endosseous dental implants with design and manufacturing concepts and materials similar to those of the predicate devices. Like the Jeil Medical Dual Top system, they have a rounded head with a groove around it for the attachment of elastics, chains or coil springs. Like the Straumann Ortho implant, the JYG Evolution™ system implants are made of CP titanium, are solid, one-piece, self-tapping implants with a transmucosal neck that has a smoothly machined surface to allow the ready attachment of epithelial tissue. JYG Evolution™ Orthodontic implants are also made of titanium alloy, but the ELI alloy is even stronger than titanium.
3. Descriptive information provided shows that the materials from which this device is made are well-established and well understood in the industry and among professional users. The materials (titanium and titanium alloy) are identical to some of the implants, and similar to those of the others made of titanium alloy.
4. The FDA “Decision-Making Process” chart was used and appears in Appendix IV.

(End of Summary)

3. Descriptive information provided shows that the materials from which this device is made are well-established and well understood in the industry and among professional users. The materials (titanium and titanium alloy) are identical to some of the implants, and similar to those of the others made of titanium alloy.

4. The FDA "Decision-Making Process" chart was used and appears in Appendix IV.

(End of Summary)

K072917

XI.

510(k) SUMMARY

Submitter: Mario Gersberg, Pres., Odontit S.A., Buenos Aires, Argentina.

Phone: +5411-4825-0221

- I. **Classification Name and Number:** Endosseous Dental Implant (DZE)
- II. **Common/Usual Name:** Implants, endosseous implants.
- III. **Proprietary Name:** J.J.G. Evolution™ Monoblock Implant system.
- IV. **Registration No.:** 9680963
- V. **Compliance with Performance Standards:** No performance standards are applicable, however we followed "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" issued May 12, 2004. The CP titanium used in these implants meets ASTM F - 67 "Specification for Unalloyed Titanium for Surgical Implant Applications," and the titanium alloy meets ASTM F - 136, "Standard Specifications for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications."
- VI. **Description of the Device:** This device is an endosseous dental implant consisting of the major component, a root-form, screw type, self-tapping implant, and accessories, designed to facilitate placing and using the implant. The accessories contact tissue for less than 1 hour and therefore are exempt from 510(k) requirements and are described only generally but are of course subject to general controls and are covered by the Quality System documents. The head of the implant has an internal square for insertion of the screw driver. The body has a cylindrical shape with tapered point with self tapping threads. The heads of this implant are provided in several shapes to meet several needs described in the indications section, including round, square, and cylindrical. The JJG Evolution™ Monoblock Implant system is made of titanium or titanium alloy, both of which meet FDA recognized consensus standards.
- VII. **Labels and Labeling:** Draft labels of the JJG Evolution™ Monoblock Implant system and instructions for use are provided, together with warnings and contra-indications.
- VIII. **Substantial Equivalence:** The JJG Evolution™ Implant system is substantially equivalent to several small implant systems currently on the market. Some of these are:

1. Zimmer One Piece Implant, Zimmer Dental Inc., K071235,
2. Endosseous Dental Implant System, K070905,
3. Mistral –One Stage Screw-Type Dental Implants, M.I.S. Implants Technologies, Inc., K070022,
4. Zimmer One-Piece Implant, Zimmer Dental Inc., K062281,
5. Fixture Microthread Osseospeed, Astra Tech, Inc., K053384.
6. Straumann Dental Implant System, Institut Straumann AG, K033984,
7. Replace One Piece Implant, Nobel Biocare UAS, Inc., K023952,
8. Odont Hex System, Odontit SA, K961631,
9. Odontit Osseointegrated Implants System, Odontit SA, K-915375.

The J.J.G. Evolution™ Monoblock Implants System is most similar to Zimmer Dental Inc.'s One Piece Implant which received concurrence of substantial equivalence from the Food and Drug Administration premarket notification submissions, K071235, K062281, and the Odontit Hex System (K961631) and Odontit Osseointegrated Implants system, cleared in K915375. Like these products, the J.J.G. Evolution™ Monoblock Implants System devices are manufactured of titanium alloy (ASTM F 136-84 titanium - 6 aluminum - 4 vanadium). The excellent biocompatibility and wear characteristics of this metal and alloy have been demonstrated by the long history of their use in surgical and dental prostheses.

Like other predicate devices, (K070905, Southern Implants; K053384, Astra Tech. Inc.; and K023952, Nobel Biocare; the J.J.G. Evolution™ Monoblock Implants are also available in Grade IV titanium (ASTM F-67). Like several of the predicate devices, the J.J.G. Evolution™ Monoblock Implants are post-type, tapered form, with spirals. Like some of them (e.g. K023972, Replace One Piece implant of Nobel BioCare; K011502, K071235, K062281, Zimmer Dental, Inc.) they are manufactured with the root form treated to roughen it or otherwise hasten osseointegration, a smooth "neck" to hasten tissue attachment, and variously shaped "top" portions to facilitate formation and attachment of prosthetic elements to replace one, or many, teeth.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use as predicate devices, they are intended to be used to replace missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla where immediate implant stability may be obtained. The device is intended for immediate implantation in extraction sites. The implant may be immediately loaded after implantation where immediate implant stability and appropriate occlusal



JAN 14 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Mario Gersberg
President
Odontit S.A.
Marcelo T de Alvear 2099
3 Dcg A-C1122AAE
Buenos Aires
ARGENTINA

Re: K072917

Trade/Device Name: J.J.G Evolution™ Mini-Implant System,
J.J.G Evolution™ Orthodontic Implant System,
J.J.G Evolution™ Monoblock Implant system

Regulation Number: 21 CFR 872.3640

Regulation Name: Endosseous Dental Implant

Regulatory Class: DZE, OAT

Product Code: II

Dated: September 20, 2007

Received: October 16, 2007

Dear Mr. Gersberg:

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

X. Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: J.J.G. Evolution™ Monoblock Implant System

This device is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It may be used for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use X
(Per 21 CFR 801 Subpart D)

or

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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510(k) Number: K072917

X. Indications for Use.

510(k) Number: (not assigned)

Device Name: JJG Evolution™ Orthodontic Implant System

Indications for Use:

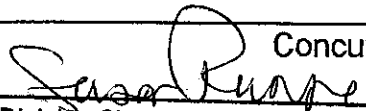
This device is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only.

Prescription Use _____
(Per 21 CFR 801 Subpart D)

or

Over-The-Counter Use _____

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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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510(k) Number: K072917

X. Indications for Use.

510(k) Number: (not assigned)

Device Name: J.J.G Evolution™ Mini-Implant System

Indications for Use:

These devices are intended for intra-bony and inter-radicular transitional applications, to permit immediate splinting stability and ongoing fixation of new or existing crown and bridge installations for full or partial edentualism such as:

Support anchors for temporary restorations during the healing and osseointegration process of permanent implants,

Immediate loading temporary abutments for repairing failing tooth and implant supported restorations,

Transitional supports for immediate replacement of missing teeth,

For use in front maxilla where 4 or more implants are splinted together, may be loaded immediately.

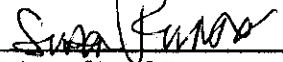
Prescription Use X
(Per 21 CFR 801 Subpart D)

or

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off) 8

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072917