K991822

AUG 1 5 2001

510(k) Summary

Introduction:

The following is a summary of Safety and Effectiveness Information. It has been prepared directly from the original Premarket Notification 510(k) submitted to the Food and Drug Administration. No information regarding safety and/or efficiency has been deleted from that submission, for this summary.

1. **Applicant's Name and Address:**

Dr. Ihde Dental AG Switzerland
Lindenstrasse 68
8738 Uetliburg
Switzerland

Telephone Number: +41 55 280 38 07
Fax Number: +41 55 280 38 61

Contact Person: Dr. Stefan Ihde:
Summary Prepared: May 20, 1999

2. **Name of the Device:**

Trade Name: Allfit® STI System
Common Name: Dental Implant System
Classification Name: Endosseous Implant (21 CFR 872.3640, Class III device).

3. **Predicate Device: Legally Marketed Devices to which Significant Equivalence SE is claimed:**

- ITI Dental Implant System® (K983742)
- ITI Wide diameter Implant (K955281)

4. **Intended use of the device**

The Allfit® STI implants are screw type endosseous dental implants made of commercially pure CP Titanium Grade 4 in conformity with ASTM standard specification F67. An adequately osseointegrated implant will result in a firm and direct connection between the specifically treated titanium surface and the living bone. The STI implants are intended to be placed in the maxillary and/or mandibular arch to support crowns, bridges or overdentures in edentulous and partially edentulous jaws of patients. The STI implants are indicated for use in areas with adequate bone supply in terms of bone quality, bone width and height. This also includes posterior areas with sufficient transverse bone and limited vertical bone height.

The implants must be used only in conjunction with the associated original components and instruments of the system according to the indications and recommendations of Dr. Ihde Dental AG. Besides the STI implants, the system includes surgical and prosthetic instruments as well as abutments. The surgical procedures must be preceded by a comprehensive and thorough patient evaluation,

preoperative diagnostics, and treatment planning. The diagnostics consists of anamnesis, clinical examination, x-ray-examination by means of Orthopantomogram as well as, if necessary remote x-ray and/or CT-examination.

5. Description of the device

The implants, produced from CP titanium 4, are available is in three diameters (3.1; 4.1 and 4.8 mm) and 6 insertion lengths: (7, 9, 11, 13, 15 and 17) respectively (8, 10, 12, 14, 16 and 18 for the long neck STI implants). The neck of the implant, which remains above the bone crest after the implantation, is a smooth machined surface to permit the attachment of epithelial tissue.

The STI implants are characterized through a rotation symmetrical structure with a thread showing high thread intervals. The thread interval depends on the implant diameter: 1 mm for the implants of 3.3 mm diameter, and 1.25 mm for the implants of 4.1 and 4.8 mm diameter. The main feature of the thread form is the 75° orientation of the surface of the thread to the implant axis, rather than parallel to the implant axis, and so directing compressive forces into the bone.

The outside contact area between the implant and its abutment shows a slope of 45° to maximize prosthesis stability, otherwise this area is flat. The implant does not possess any inside or outside hex. The rotation secured screw (against the abutment) occurs over the friction of the inside cone, hereby the inside screw thread M2 pulls against the cone. The creation of high adhesion friction fit leads to a secure connection of implant and abutment. Single crowns can be screwed on the implant, if secured abutments (for example OSA STI) are used.

Allfit STI-implants are available in two neck heights: 1.8 mm and 2.8 mm, however the total length of the implant is always identical. Therefore the endosseous part is smaller in the case of 2.8mm neck height. The choice between the 2 alternatives depend on the clinical situation of the soft tissue: In the molar region, thick soft tissues are usually suitable for the long neck, while in the anterior region, esthetic aspects and thin soft tissue are suitable for smaller neck portions.

6. Summary of Technological Characteristics:

Features	Subject Device		Predicate Devices	
	AllFit®STI		ITI Wide diameter Implant (K955281)	ITI Dental Implant System (K983742)
Intended Use				
	Implants intended to be placed in the maxillary and/or mandibular arch to support crowns, bridges or overdentures in edentulous & partially edentulous jaws			
Indications for use				
	Implants used for all indications requiring oral endosseous implants for functional, aesthetic rehabilitation of edentulous & partially dentate upper or lower jaws			
Material				
	Commercially Pure CP Titanium Grade 4			
Design				
	External screw threads			
External screw threads				
	75° orientation to the implant axis			
Diameter				
	3.3; 4.1; 4.8 3.3 mm as option in alveolar ridges of limited width		5.6	3.3; 4.1; 4.8
Endosseous Lengths	**Short Neck**	**Long Neck**		
	7.0 9.0 11.0 13.0 15.0 17.0	8.0 10.0 12.0 14.0 16.0 18.0	8.0 10.0	8.0 10.0 12.0 14.0 16.0
Sterility				
	Gamma Irradiation, Co60			
One stage surgical protocol	**Short Neck**	**Long Neck**		
	YES/NO	YES	YES	YES
Implant/abutment taper				
	YES		YES	YES
External Hex				
	NO		NO	NO
TPS coating				
	NO		YES	YES
Sand Blasting				
	YES		NO	NO

7. Basis for Substantial Equivalence

The Allfit® STI implant system is significantly equivalent to the cleared, Straumann ITI Implant System (K955281, K983742). The STI implant system is in terms of design, dimensions (implant thickness, screw diameters, screw thread heights & rises), material composition, sterility method, intended use, abutments, accessories, indications for use and target population, very similar to the cleared Straumann ITI system.

The endosseous surface of the STI implants is first mechanically shaped, then cleaned and sand blasted with Al-Oxide. This surface treatment method enables the increase of the implant surface, which significantly improve the grow of the bone after the implantation. In contrast to the STI implants, the cleared Straumann ITI implant portion to be implanted into the bone has an anchorage surface of a Titanium Plasma Sprayed TPS coating of 20-30 µm thickness. This process yields also to very rough, bone friendly implant surfaces. In contrast to the sand blasting method (STI), the TPS method is complex and technically sensible. If this method is not conducted adequately, this may lead to undesired caves and niches within the surface of the implant. If this occurs, it is possible, that these caves and niches can not be cleaned effectively and therefore could offer a good substratum for bacteria. In this respect, the sand blasting method offers the assurance for a rough, cave-free surface.

The STI implants are produced in one single piece with a small grip, which is then locked into the cover of the primary packaging. Before the actual implantation, the implant is first screwed on the insertion tool and then broken off from its grip. After breaking the grip, a non treated rise of pure Titanium with approximately 0.6 mm diameter and 0.2 mm height remains on the break off area of the implant. This method has been appreciated by the practicing dentists, because it enable a secure functioning and permit to avoid any contact with other materials or substances. In the case of the Straumann ITI implants, the implant hangs within a Titanium husk ring, separating the implant from the packaging material.

The Allfit STI RT LN (long neck) implants are intended, - similar to the previously cleared Straumann ITI-Implants-, for single stage protocols. However, in rare cases, it may be possible to cover the tissue over the long neck and change the procedure to two stages. The Allfit STI short neck implants show a sand blasted surface, which is 1mm longer than the long neck type. This leads to a shorter neck: instead of 3,3 mm the total neck portion is 2.3 mm only. Consequently it is easier to cover the implant after placement with soft tissue and change the protocol to a two stage procedure. In general, with the short neck, Allfit STI RT implant, are suitable for both types of surgery: One and two stage. The short neck makes it easier to cover the implant after placement .

8. Premarket Notification Certification and Summary:

I certify, in my capacity as Chief Executive Officer of Dr. Ihde Dental AG, that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the Allfit® STI implants. I further certify that I am aware of the types of problems to which the Allfit® STI implants are susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness about the Allfit® STI implants is complete and accurate.

Failure to osseointegrate or loss of osseointegration can be caused by:

- Improper patient selection, patients with systemic diseases which affect bone physiology, patients with habits such as bruxing or clenching, patients who are physically or psychologically unable to carry out proper implant hygiene, patients with heavy smoking or alcohol use.
- Improper surgical technique such as overheating of bone.
- Improper case planning or restorative technique: Overloading of implants through improper placement, Use of an insufficient number of implants or excessive cantilever.
- Improper implant processing by the manufacturer, improper handling by the dentist resulting in contamination.

Fracture of implants can occur either on insertion of screw type implants due to excessive torque (improper surgical technique such as an error in drill selection) or in service due to loss of bone.

Fracture of abutments and abutment screws occurs in implant systems and is usually attributed to factors within the control of the implant team, such as lack of passive fit of the restoration or excessive cantilever, or within the control of the patient, such as bruxing.

There are other types of safety and effectiveness problems which have beer observed for endosseous dental implant systems. These are:

- local soft tissue degeneration and bone resorption
- paresthesia
- perforation of the maxillary sinus, perforation of labial and lingual plates
- local and systemic infection
- prosthetic framework fracture, bone fracture
- nerve injury, injury to adjacent teeth and their supporting bone
- oroantral or oronasal fistula
- gingival hyperplasia
- soft tissue overgrowth
- perforation of the gingiva by the healing screw
- mucosal abscess
- displacement of the implant into the mandibular canal
- hemorrhage of the floor of the mouth due to transection of the sublingual artery and breakage of drill tip, requiring surgical removal.

May 24, 1999.

Dr. Stefan K. Ihde
Chief Executive Officer
Dr. Ihde Dental AG

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 5 2001

Dr. Mourad Baraket
Carthago International Solutions, Inc.
70 Battery Place
Riverwatch Suite 406
New York, New York 10280

Re: K991822
Trade Name: Allfit Implant System, Short Neck, Model ST1
Rt Length, AL
Regulatory Class: III
Product Code: DZE
Dated: September 20, 1999
Received: September 22, 1999

Dear Mr. Baraket:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number: K991822

Device Name: Allfit STI Implant System

Indications for Use

The Allfit® STI implants are screw type endosseous dental implants made of commercially pure CP Titanium Grade 4. Provided the existence of adequate bone supply in terms of bone quality, bone width and height, Allfit® STI implants can be used for all indications requiring oral endosseous implants for functional, aesthetic rehabilitation of edentulous and partially dentate upper or lower jaws. The restoration may comprise:

- Single teeth replacement for gaps up to the width of Incisive and Premolars
- Bridge substitution in edentulous, partially or fully dentate jaws
- Bracing for orthodontist regulation systems
- Providing retention and support for dentures through bars and/or ball attachment

The implants must be used only in conjunction with the associated original components and instruments of the system according to the indications and recommendations of Dr. Ihde Dental AG. The surgical procedures must be preceded by a comprehensive and thorough patient evaluation, preoperative diagnostics, and treatment planning.

Indications for 3.3 mm ∅ STI implants:

STI screw implants with an external diameter of 3.3 mm are considered options for placement in alveolar ridges of limited width (5-6 mm). Since the 3.3 mm diameter STI implants exhibit lower mechanical strength values compared to the 4.1 mm and 4.8 ∅ STI implants, the 3.3 mm diameter screw implants should only be used for indications involving minimal loading.

Indications for 4.8 mm ∅ STI implants:

4.8 mm ∅ STI screw implants can be used for all indications requiring oral, endosseous implants for functional, aesthetic rehabilitation of edentulous and partially dentate upper or lower jaws with a width of 7 mm or more.

It is recommended to always use the longest and widest (diameter) implant. Hereby the possibly influencing forces must be taken into account. It is therefore recommended, not to use implants with small diameters in the posterior side for single teeth implantation. The anatomical and prosthetic conditions have to be taken into consideration.

For a proper use of the STI implants, the consultation of The Allfit® STI instructions for use, provided by Dr. Ihde Dental AG, including the list of absolute, relative and local contraindications, is absolutely indispensable.

Prescription Use ✓
(Per 21 CFR 801.109)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991822