

K955281

ATTACHMENT 10 - 510(k) Summary

1. Applicant's name and address

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2. Name of the device

Trade Name: ITI Wide Diameter Implant
Common Name: Endosseous dental implant and accessories
Classification Name: Endosseous dental implant

3. Legally marketed devices to which equivalence is claimed (predicate devices)

ITI 4.1 mm Solid Screw Implant (K894595, K920768)
Nobelpharma Brånemark System - 5.5 mm Fixture (K926501)
Implant Innovations, Inc. wide diameter implants (K number unknown)
Lifecore Biomedical Wide Diameter Implant (K944068)

4. Description of the device

Implants

The ITI Wide Diameter Implant is a one-stage root-form design made of commercially pure titanium Grade 4 conforming to ASTM Standard Specification F67. It differs from the previously cleared ITI 4.1 mm Solid Screw Implant (K894595, K920769) only in the diameter. The portion of the implant intended to be implanted into bone has an anchorage surface of a titanium plasma-sprayed coating 20 - 30 μ m thick. The neck of the implant, intended to remain above the crest of the bone upon implantation, is a smooth machined surface to allow for the attachment of epithelial tissue. It is 2.8 mm in height and tapers to 4.8 mm in diameter at the coronal end to permit all standard ITI abutments to be used. The abutment mates with a tapered internal cone of the implant; at its apex is a threaded region into which the matching thread of the abutment is screwed. The implant shoulder, which forms a mating surface for prosthetic components, is machined with a 45° chamfer to maximize prosthesis stability. The diameter at the coronal end, the internal taper, and thread for attachment of the abutment and the 45° chamfer are identical to those of the ITI 4.1 mm Solid Screw Implant.

For the junction between the primary part (the implant) and the secondary part (the abutment), a cone-screw construction is used, which helps ensure an accurate marginal fit within the implant, reducing risk of loosening or rotation of the abutment. All ITI abutments have a tapered cone-to-screw base which screws into the coronal portion of the implant and creates a mechanically locking friction fit (similar to Morse taper, a principle that has been used in machine shops for many years).

The external shape of the ITI Wide Diameter Implant consists of a solid body of 4.95 mm diameter with an external spiral screw having a major diameter of 5.6 mm. The principal feature of the thread form is the fact that the compressive (flank) surface of the thread is oriented at 75° to the implant axis, directing compressive forces into the bone, rather than parallel to the implant axis. The thread pitch and thread form are identical to those of the ITI 4.1 mm Solid Screw Implant. The most apical 2 mm of the

implant and the first 1.5 mm below the crest of the bone have no threads. The apex has a near-hemispherical shape. The implant is manufactured in sink depths (the depth intended to be implanted into bone, excluding the 2.8 mm neck) of 8 and 10 mm.

Accessories

The surgical technique intended for the implant includes initial use of the same ITI 2.2 mm and 2.8 mm pilot drills as are used for other ITI solid screw implants, followed by the use of the standard ITI 3.5 mm twist drill. Twist drills of 4.2 mm and 5.0 mm diameter, included in this submission, are then used, followed by a thread tap. All ITI twist drills and thread taps are made from martensitic stainless steel (DIN 1.4112, equivalent to AISI 440B) and include grooves to show the correct placement depth for each implant length. The depth gauge provided for use with the ITI Wide Diameter is made from austenitic stainless steel (DIN 1.4305, equivalent to AISI 303).

5. Intended use of the device

The device is intended for surgical placement in maxillary and/or mandibular arch to support crowns, bridges, overdentures in edentulous or partially edentulous patients. As with the predicate devices, the subject device is indicated for use in areas with available bone, including posterior regions with sufficient transverse bone and limited vertical bone height.

6. Summary of technological characteristics

Feature	Subject Device	Predicate Devices			
	ITI Wide Diameter Implant	ITI 4.1 mm Solid Screw Implant (K894595, K920768)	Nobelpharma Brånemark System 5.5 mm Fixture (K926501)	Implant Innovations Wide Diameter Implant (K# unknown)	Lifecore Biomedical Wide Diameter Implant (K944068)
Intended Use					
Surgical placement in maxillary and/or mandibular arch to support crowns, bridges, overdentures in edentulous or partially edentulous patients	YES	YES	YES	YES	YES
Material					
CP Ti	YES	YES	YES	YES	YES
Design					
External screw threads	YES	YES	YES	YES	YES
Diameter (mm)	5.6	4.1	5.5	5.0, 6.0	5.0, 5.5, 6.0
Lengths implanted (mm)	8.0 10.0	8.0 10.0 12.0 14.0 16.0	6.0 8.0 10.0 12.0	7.0 8.5 10.0 13.0	8.0 10.0 13.0
One stage implant/abutment taper	YES	YES	NO	NO	NO
External hex	NO	NO	YES	YES	YES
TPS Coating	YES	YES	NO	NO	NO

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7. Nonclinical tests

A comparison was made between the strength of the ITI Wide Diameter Implant and that of the ITI 4.1 mm Solid Screw Implant (a predicate device), loaded at 45° to the implant axis and at 90° to the implant axis. Implants were imbedded in (polymethylmethacrylate) PMMA, ITI solid abutments were inserted in the implants and stainless steel test couplings (simulating prosthetic restorations) were mounted on the abutments. Tests were conducted by applying monotonic increasing loads to the test couplings until loads decreased or failure occurred. Force vs. deflection curves were recorded for each test and the mode of failure was noted.

The study showed that failure loads of ITI Wide Diameter Implants when loaded at 45° or at 90° consistently exceed those of ITI 4.1 mm Solid Screw Implants. These results demonstrate that the ITI 5.6 mm diameter solid screw implant is substantially stronger in bending than the previously cleared ITI 4.1 mm diameter solid screw implant.

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