

K962647
Oct. 7, 1996

ATTACHMENT 9 - 510(k) Summary

1. Applicant's Name and Address

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2. Name of the Device

Trade Name: ITI Angled Abutment
Common Name: Abutment for endosseous dental implant
Classification Name: Accessory to a dental implant (21 CFR 872.3640)

3. Legally Marketed Devices to which Equivalence is Claimed (Predicate Devices)

1. ITI Angled Abutment (K941393)
2. Brånemark Angled Abutment (K905434)
3. Calcitek Angled Abutment (K number unknown)
4. 3i Angled Abutment (K number unknown)

4. Description of the Device

The ITI angled abutment is placed into the dental implant to provide support for the prosthetic restoration. The subject device of this 510(k) is a modification of the ITI Angled Abutment, previously cleared by FDA under K941393 for angulation correction in the saggital plane of the anterior maxilla. The intended use of the modified angled abutment is for angulation correction in all areas of the oral cavity.

The modified angled abutment is available in 15° and 20° angles and is made from commercially pure Grade 4 titanium (cold worked) which conforms to ASTM Standard Specification F67. The abutment is provided non-sterile in medical grade heat-sealed packaging.

The basal portion of the modified angled abutment has an 8° conical taper which fits into the coronal portion of the ITI implants. The abutment is held in place with a screw located in the basal portion of the abutment. This screw is also composed of Grade 4 titanium. The abutment is manufactured out of a single piece of titanium. The screw and suspension ring are mounted into the basal portion of the abutment. The coronal aspect of the abutment has an occlusal thread for the impression coping and a lateral screwdriver access hole.

Accessories

A **positioning aide** is available to be inserted into the top of the abutment to assist the clinician in properly orienting the direction of angulation upon abutment insertion. The positioning aide is removed from the abutment after the basal screw has engaged the implant. The positioning aide is composed of anodized aluminum and is for single use only. A **screwdriver** is required to tighten the basal screw of the abutment into the implant through a lateral access hole in the coronal portion of the

abutment. The **impression cylinder** and **transfer pin** are composed of stainless steel. The impression cylinder is mounted into the occlusal threads on the coronal portion of the abutment when the impression is taken. The impression cylinder is then removed from the abutment and attached to the transfer pin. The impression cylinder and transfer pin are reinserted into the impression material and the cast is poured, incorporating the transfer pin and obtaining a precise replication of the abutment in the implant in the mouth. If the clinician decides to screw retain the prosthesis, as opposed to cementing, the **occlusal screw** is required to secure the final restoration to the abutment. The screw is composed of Grade 4 titanium. If occlusal space allows, the **extension shell** can be placed over the abutment to serve as an extended screw bed and screw channel for the occlusal screw.

5. **Intended Use of the Device**

The modified angled abutment is indicated to be used in cases where the angle of placement of the implant requires an angled reconstruction for an aesthetic result. The abutment can be used to restore both crowns for single tooth replacements and bridges for bound situations.

6. **Summary of Device Compared to Predicate Devices**

	Subject Device	Predicate Devices			
	ITI Modified Angled Abutment	Previously Cleared ITI Angled Abutment	Brånemark Angled Abutment	Calcitek Angled Abutment	3i Angled Abutment
Intended Use					
Provide support for dental prosthesis	Yes	Yes	Yes	Yes	Yes
For use with cemented restorations	Yes	Yes	Yes	Yes	Yes
For use with screw-retained restorations	Yes	Yes	No	No	No
Design					
Screwed into implant to be used as a base for dental prosthesis	Yes	Yes	Yes	Yes	Yes
Available degrees of angulation	15° and 20°	15° and 20°	17° and 30°	15° and 25°	15°, 25°, and 35°
Composition					
Composed of Titanium	Yes	Yes	Yes	Yes	Yes
K Number		K941393	K905434	unknown	unknown