

The Implant Center Of The Palm Beaches

Surgical and Non-Surgical Periodontics, Oral Implantology,
Tissue Regeneration



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K961386

Re: 510(k) Summary

SEP 25 1996

To Whom It May Concern:

Pursuant to your request, information regarding the above-referenced PMN-510(k) summary for substantial equivalence of the above-referenced document is enclosed.

The above-referenced devices have been reviewed by the CDRH, as well as the Office of Compliance and have received a substantial equivalence letter.

Predicate Devices

Dental Imaging Associates - Pre-market notification #K902433
Dental Imaging Associates - K902434
Dental Imaging Associates - K902435
Implant Innovations - Pre-angled abutments - K932123

Predicate Devices For Wide Body

Nobelpharma - K925766
Nobelpharma - K934826
Nobelpharma - K934495
Implant Innovations - K933969
Implant Innovations - K934126
Implant Innovations - K933462

Device Description:

Endosseous implant system consists of implants, tools and abutments. This submission includes pre-machined angulated abutments less than 30 degrees, specifically 15 and 25-degree abutments are included. In addition, in the wide-body abutment series, a series of one and two-piece prosthetic abutments are included in 4, 5 and 6 mm. platform diameters. These devices are similar in their use in that they are placed on top of the implant fixtures after the appropriate integration phase and prosthetic attachments are fabricated to these abutments.

INTENDED USE:

The wide body abutments and pre-angled abutments are similar to those of other implant systems in their intended use which is to facilitate the prosthetic phase and installation of the prosthesis for the patient.

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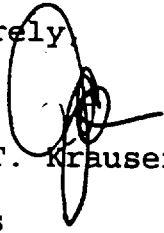
TECHNOLOGY CHARACTERISTIC SUMMARY:

Design, material, manufacturing process, gamma sterilization, geometry and service and materials are similar to predicate devices currently on the market.

This PMN includes devices to correct angulation changes as well as wide body implants for the prosthetic phase of the case. The materials are ASTM standard B-348-93 titanium grade 3, 4 and titanium alloy ELI-grade 5. GMP guidelines are in place to track the product development and manufacturing processes. Food & Drug Administration, Office of Compliance has inspected and deemed all stages of the GMP process are in compliance with GMP standards.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,



Jack T. Krauser, D.M.D.-

JTK/ms