Analyzing Approval Process of Substantial Equivalence Devices Based on Previously Approved Devices Across Korea, USA, Japan, EU, AHWP Members

OSSTEM IMPLANT

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Substantial Equivalence

The 510(k) Program : Evaluating Substantial Equivalence in Premarket Notification [510(k)]

underlie the substantial equivalence determination in every 510(k) review. The standard for a determination of substantial equivalence in a 510(k) review is set out in section 513(i) of the FD&C Act, which states:

> Substantial Equivalence
>
> (i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device
>
> (i) has the same technological characteristics as the predicate device, or
>
> (ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.
>
> (B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

Substantial Equivalence

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Safety and effectiveness factor into both parts of the FDA's review. First, FDA must find that the intended use of the device and its predicate are "the same." As discussed in the Intended Use Section of this guidance, differences in the indications for use, such as the population for which a device is intended or the disease a device is intended to treat do not necessarily result in a new intended use. Such differences result in a new intended use when they affect (or may affect) the safety and/or effectiveness of the new device as compared to the predicate device and the differences cannot be adequately evaluated under the comparative standard of substantial equivalence. (See **Section IV.D.**)

Second, when comparing a new device to a predicate device, FDA must find that the two devices have "the same technological characteristics," or that a "significant change in the materials, design, energy source or other features of the device" does not raise different questions of safety and effectiveness and that the device is as safe and effective as a legally marketed device.

Substantial Equivalence Matrix

Substantial Equivalence Matrix

General Description

[redacted] is used for connecting with implanted fixture to prevent foreign material intrusion during the osseointegration and connecting with [redacted]

Similarities to, and differences from, other commercially available devices:

[redacted] is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

The following table outlines the similarities and differences between the [redacted] and predicate devices.

Name	[redacted]				[redacted]	
510(k)	Proposed				[redacted]	
Manufacturer	OSSTEM Implant Co., Ltd.				OSSTEM Implant Co., Ltd.	Same
Design						Similar
Material	Titanium alloy Ti-6Al-4V	Titanium alloy Ti-6Al-4V	Titanium alloy Ti-6Al-4V	Titanium alloy Ti-6Al-4V	Titanium alloy Ti-6Al-4V	Same
Intended use	[redacted] is a metal device intended for use with a dental implant to stabilize and support of bone graft in dento-alveolar bony defect sites.					Same
Compatible device	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Same
Compatible fixture	[redacted] (K081[redacted])	[redacted] (K081[redacted])	[redacted] (K123[redacted])	[redacted] (K123[redacted])	[redacted] (K123[redacted])	Same / Different

Substantial Equivalence Matrix

表3. 設計の基礎とした既承認医療機器と申請品目との差分に関する情報

(注1)	申請品目	既承認医療機器	差分に関する情報 (注２)
一般的名称			
販売名			
会社名			
承認番号			
承認年月日			
使用目的、効能又は効果			
形状、構造			
原理			
原材料			
・・・・・・・・・・			
・・・・・・・・・・			

Substantial Equivalence Matrix

1.2.3 既承認医療機器との差分の概要

以下に設計の基礎とした既承認医療機器と申請品目との差分に関する情報を示す。

表1.2.3 設計の基礎とした既承認医療機器と申請品目との差分に関する情報

1) [redacted] フィクスチャー

	申請品目	類似品1	類似品2	類似品3	類似品4	類似品5	差分に関する情報
類別	整形用品						
一般的名	歯科用インプラン	形状及び	フィクスチャー	フィクスチャー	1.インプラント体	Type FR	本品及び類似品1、

	申請品目	類似品1	類似品2	類似品3	類似品4	類似品5	差分に関する情報
類別							
一般的名称							
ｸﾗｽ分類							
販売名							
会社名							
承認番号							
承認年月日							
使用目的、効能又は効果							
形状及び構造							
原理							
主な原材料							
表面処理							
使用方法							
資料の出典							

Category

General Device Name

Classification

Product Name

Manufacturer Name

Approval / License Number

Approved / Licensed Date

Intended Use, Effetiveness

Appearance, Structure

Principle

Main Material

Surface Treatment

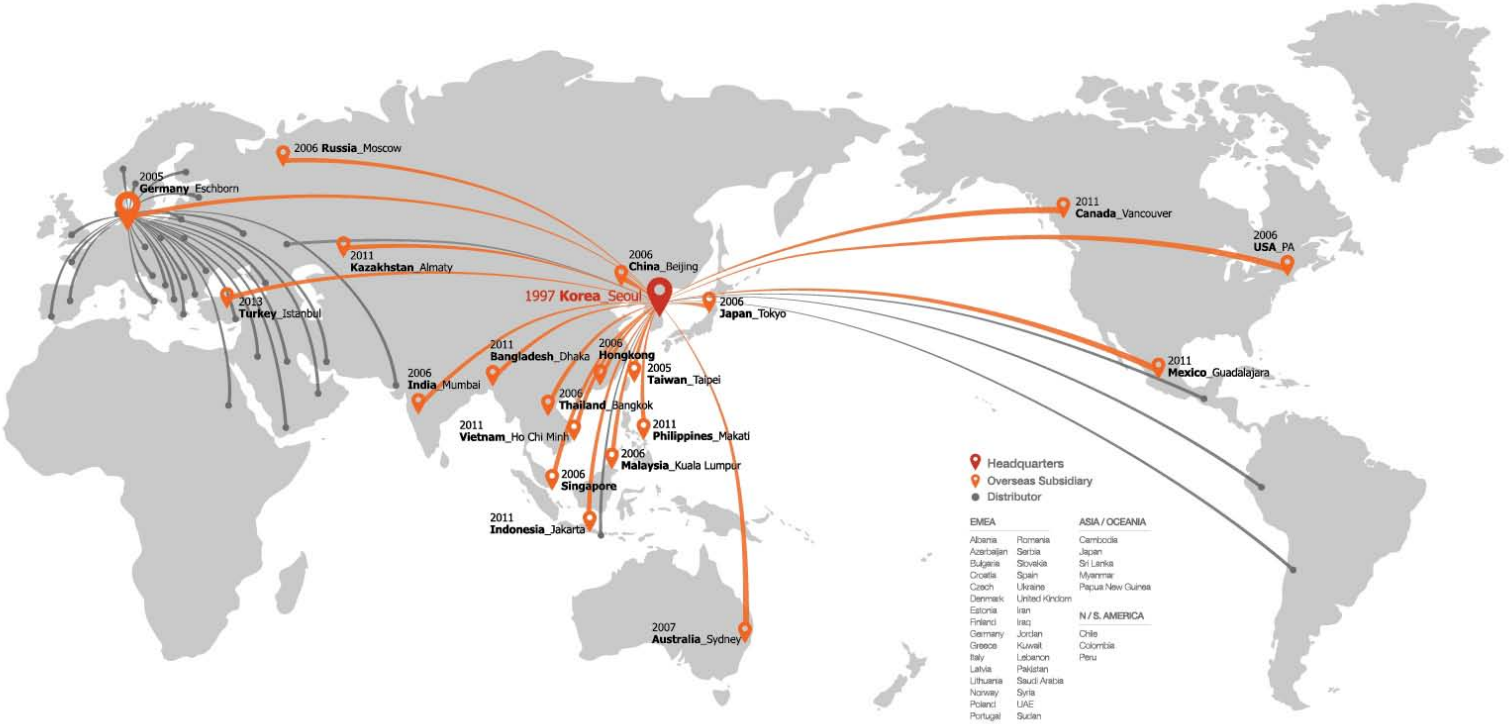
Instruction for Use

Information Source

Introduction - OSSTEM IMPLANT & Product

OSSTEM IMPLANT

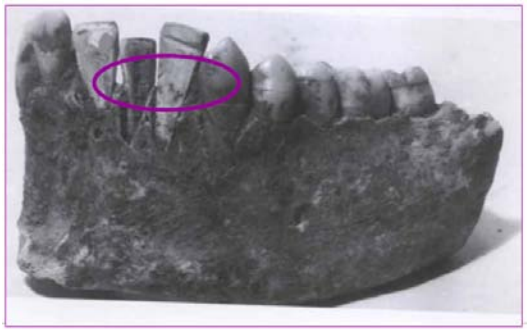
OSSTEM World Wide



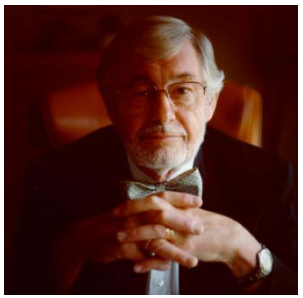
OSSTEM IMPLANT

Introduction - OSSTEM IMPLANT & Product

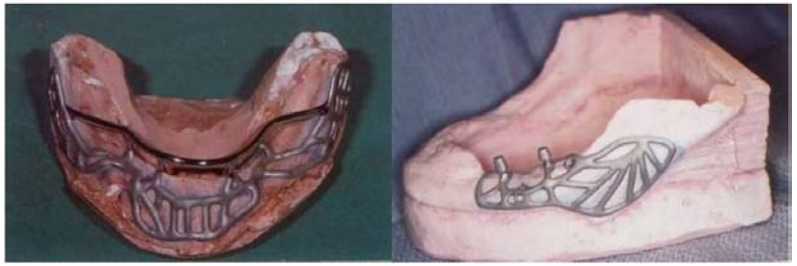
Maya (AD 600)



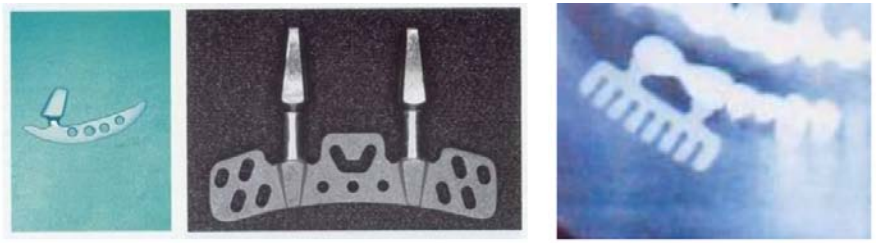
Branemark implant (1952)



Subperiosteal implant (AD 600)



Blade implant (1960 ~ 1970)



Dentium For Dentists By Dentists

DENTIS

MEGAGEN

Neo Biotech Satisfaction to Dentists

DIO

BIOTEM DENTAL IMPLANT SYSTEM

Nobel Biocare

straumann

ASTRATECH DENTAL

3i A BIOMET COMPANY

BIOHORIZONS

zimmer dental

DENTSPLY FRIADENT CERAMED

BEGO SEMADOS

Implant Direct simply smarter.

Innova SYBRON DENTAL SPECIALTIES

bicon DENTAL IMPLANTS

mis

camlog

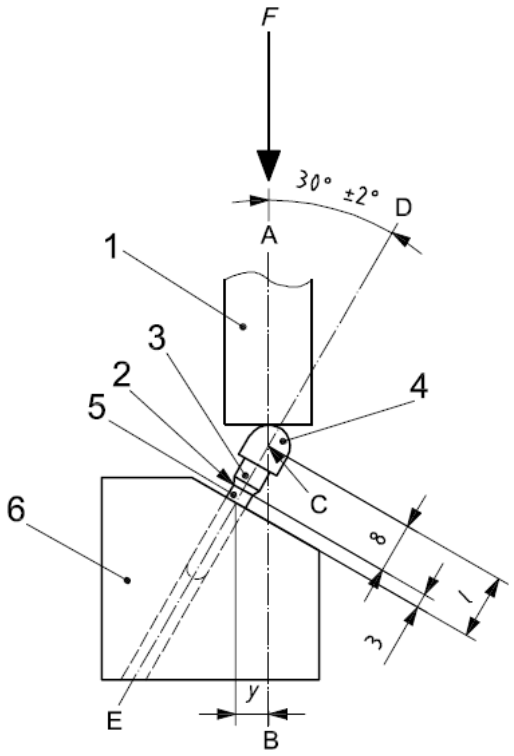
anthogyr

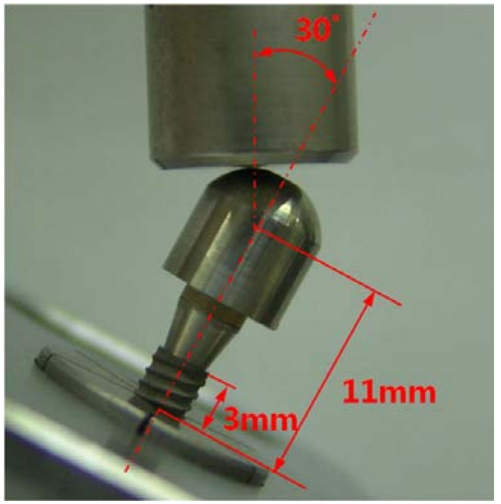
LIFECORE BIOMEDICAL

OSSTEM IMPLANT

Case 1.

Fatigue test result comparison





Predicated Device

400 ~ 600 Ncm

VS

Proposed Device

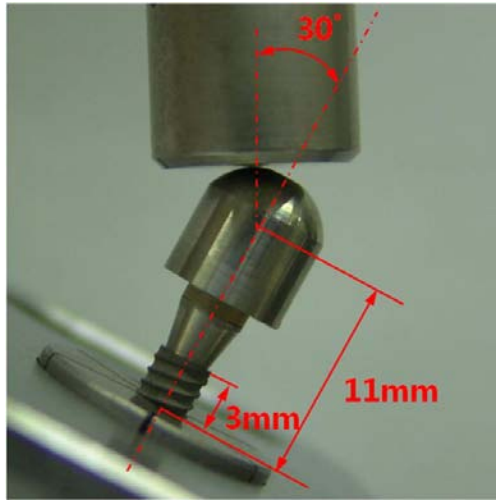
About 800 Ncm

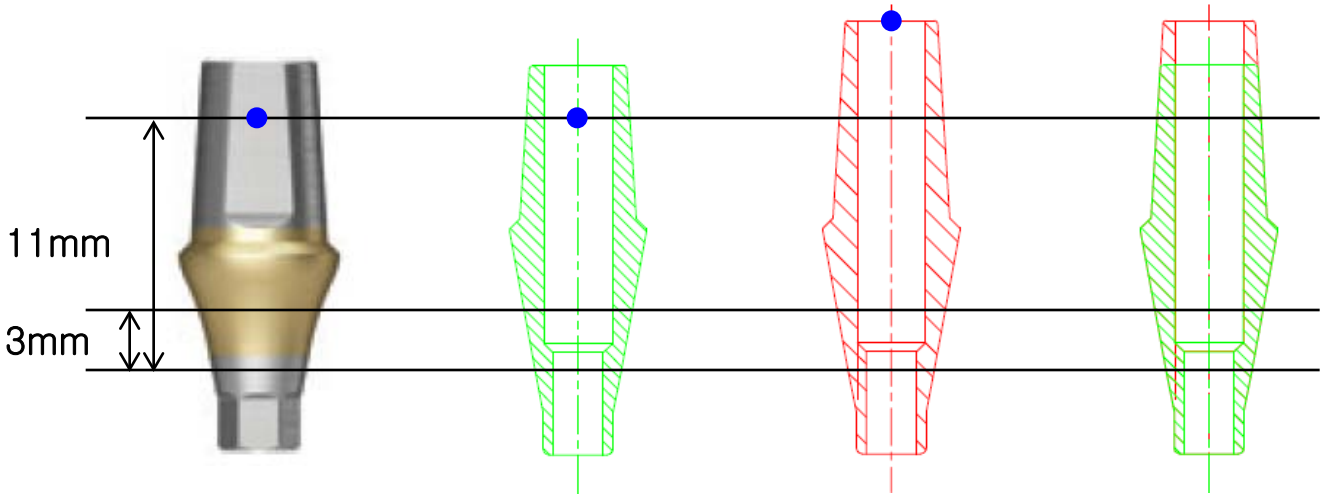
NSE (Non Substantial Equivalence)? YES!!!

But not safe and effective as a Dental Implant?? NO!!!

Case 2.

Fatigue test – loading point





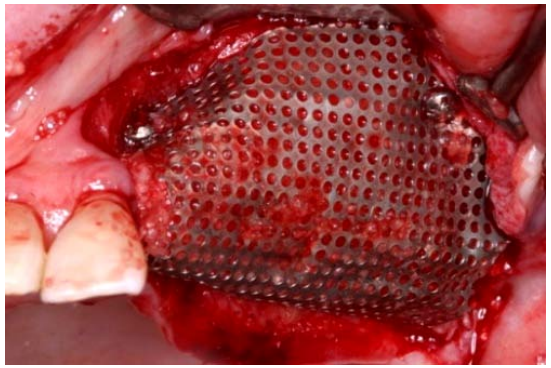
Test condition is disadvantageous to proposed device

How substantial equivalence can be evaluated?

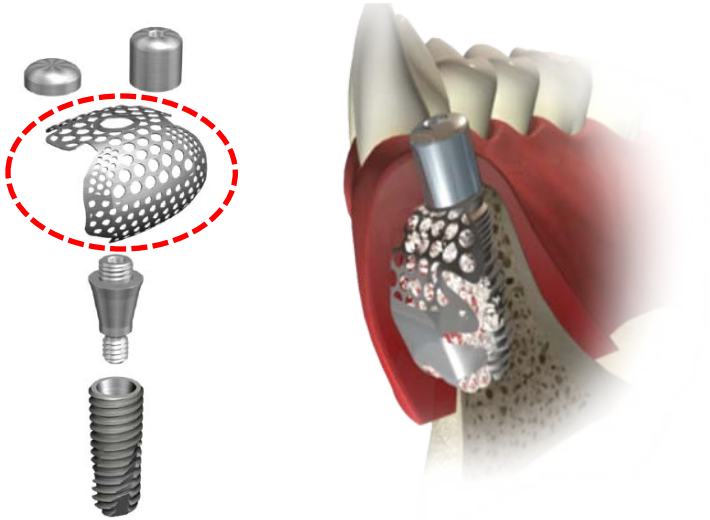
Case 3.

Titanium Membrane for GBR (Guided Bone Regeneration)

Predicated Device



Proposed Device



Same “Intended Use” and made with “Same Material (Titanium)”

Country A :
Such system is totally new. Therefore implantation test (26 weeks) is required

Country B :
Such system is totally new. Therefore clinical study (3 year) is required

Consideration

- What is main purpose of substantial equivalence?

  Safety and effectiveness? or Exemption of required test report?
- Approved product in other country. Available for substantial equivalence?
- If available, which country can be qualified?
- There is no predicated device, but approved in other countries and long stand technology is applied. New technology is applied to the device?
- Definition of “Long Stand Technology”?

Thanks for your attention