FDA 510(k) Premarket Notification

K160213 s-Clean Tapered II RBM Implant System

CLEARED

Jun 21, 2016
144 days to decision

K160213 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k160213/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 29, 2016
Decision date	Jun 21, 2016
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dentis Co., Ltd.**
Location	Dalseo-Gu, KR
Contact	Sun Chul Shin
Website	https://www.dentis.co.kr
510(k) history	37 submissions · 37 cleared · 2008-2026

Dentis Co., Ltd. is a Dental device manufacturer based in Dalseo-Gu, South Korea. The company has received FDA 510(k) clearances from total submissions. All submissions focus on Dental devices, with a regulatory history spanning from 2008 to 2026. The company remains active, with recent clearances demonstrating ongoing product development and market engagement. Dentis specializes in dental implant systems, abutments, and associated clinical equipment. Recent cleared devices include implant fixtures, abutment components, scanning and healing systems, and dental chairs, ref...