FDA 510(k) Premarket Notification

CLEARED

K130221 HERO II DENTAL IMPLANT SYSTEM, UI DENTAL IMPLANT SYSTEM

Mar 21, 2013
51 days to decision

K130221 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k130221/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 29, 2013
Decision date	Mar 21, 2013
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medimecca Co., Ltd.**
Location	Anaheim, CA, US
Contact	Priscilla Chung
510(k) history	4 submissions · 4 cleared · 2013-2020