FDA 510(k) Premarket Notification

K140051 KJ EXTERNAL IMPLANT SYSTEM

CLEARED

Oct 30, 2014
294 days to decision

K140051 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k140051/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 9, 2014
Decision date	Oct 30, 2014
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kj Meditech Co., Ltd.**
Location	Fullerton, CA, US
Contact	Priscilla Chung
510(k) history	12 submissions · 12 cleared · 2011-2022