FDA 510(k) Premarket Notification

K112787 KERATOR

CLEARED

Aug 8, 2012
317 days to decision

K112787 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k112787/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Sep 26, 2011
Decision date	Aug 8, 2012
Days to decision	317 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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