FDA 510(k) Premarket Notification

K190048 UF(II) Anatomic abutment

CLEARED

Sep 30, 2019
263 days to decision

K190048 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k190048/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jan 10, 2019
Decision date	Sep 30, 2019
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dio Corporation**
Location	Los Angeles, CA, US
Contact	Jiae Park
510(k) history	14 submissions · 14 cleared · 2010-2023