FDA 510(k) Premarket Notification

CLEARED

K192218 Custom Legacy and Custom InterActive Titanium Abutments

May 8, 2020
267 days to decision

K192218 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k192218/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Aug 15, 2019
Decision date	May 8, 2020
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Implant Direct Sybron Manufacturing, LLC**
Location	Calabasas, CA, US
Contact	Reina Choi
510(k) history	17 submissions · 17 cleared · 2013-2023