

**K192218 Custom Legacy and Custom InterActive Titanium
Abutments**May 8, 2020
267 days to decisionK192218 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192218/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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