

K191458 Legacy SMARTBase AbutmentsOct 10, 2019
132 days to decisionK191458 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k191458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	May 31, 2019
Decision date	Oct 10, 2019
Days to decision	132 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/k191458/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026