

K192015 Faico Dental Implant SystemApr 3, 2020
249 days to decisionK192015 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k192015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 29, 2019
Decision date	Apr 3, 2020
Days to decision	249 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Faico Medical, LLC
Location	Boca Raton, FL, US
Contact	Hernan Dario Fernandez
510(k) history	3 submissions · 3 cleared · 2020-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192015/> 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