FDA 510(k) Premarket Notification

K240803 Surgikor Fixation One, Abutment Blanks and Abutments

CLEARED

Sep 12, 2024
171 days to decision

K240803 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k240803/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 25, 2024
Decision date	Sep 12, 2024
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Surgikor, LLC**
Location	Los Angeles, CA, US
Contact	Jeremy Barbanell
510(k) history	2 submissions · 2 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	**Blackwell Device Consulting**
Contact	Angela Blackwell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov