FDA 510(k) Premarket Notification

K232350 Stryker Facial iD System

CLEARED

Jan 13, 2024
159 days to decision

K232350 · Product code: **JEY** · Dental
Source: https://www.510kdatabase.net/k232350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Aug 7, 2023
Decision date	Jan 13, 2024
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Craniomaxillofacial**
Location	Portage, MI, US
Contact	Jonathan Schell
510(k) history	3 submissions · 3 cleared · 2007-2024