FDA 510(k) Premarket Notification

K202969 Biomet Microfixation OmniMax MMF System

CLEARED

Aug 5, 2021
309 days to decision

K202969 · Product code: **JEY** · Dental
Source: https://www.510kdatabase.net/k202969/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Sep 30, 2020
Decision date	Aug 5, 2021
Days to decision	309 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Microfixation**
Location	Jacksonville, FL, US
Contact	Lauren Jasper
510(k) history	24 submissions · 24 cleared · 2012-2024