FDA 510(k) Premarket Notification

K093719 PRO-FIX PRECISION FIXATION SYSTEM MODEL PFM#, PFB#, PFT#

CLEARED

Mar 1, 2010
89 days to decision

K093719 · Product code: **DZL** · Dental
Source: https://www.510kdatabase.net/k093719/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Intraosseous (DZL)
Date received	Dec 2, 2009
Decision date	Mar 1, 2010
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Osteogenics Biomedical, Inc.**
Location	Lubbock, TX, US
Contact	DUSTYN WEBB
510(k) history	8 submissions · 8 cleared · 1999-2021