FDA 510(k) Premarket Notification

K021342 NORMED BI-DIRECTIONAL/MULTIDIRECTIONAL JAW DISTRACTOR

CLEARED

Aug 1, 2002
94 days to decision

K021342 · Product code: **JEY** · Dental
Source: https://www.510kdatabase.net/k021342/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Apr 29, 2002
Decision date	Aug 1, 2002
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osteomedics, Inc.**
Location	Paramus, NJ, US
Contact	ALBERT ENAYATI
510(k) history	9 submissions · 9 cleared · 2001-2003