

K140978 OSTEOMED LOW PROFILE ORBITAL FLOOR PLATE SYSTEM

Dec 18, 2014
246 days to decision

K140978 · Product code: JEY · Dental
Source: <https://www.510kdatabase.net/k140978/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Bone (JEY)
Date received	Apr 16, 2014
Decision date	Dec 18, 2014
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteomed
Location	Addison, TX, US
Contact	Ally Baduel
510(k) history	12 submissions · 12 cleared · 2012-2021

510k Database - www.510kdatabase.net
 Device record: <https://www.510kdatabase.net/k140978/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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