FDA 510(k) Premarket Notification

K031708 OSTEOMED MAXILLARY/LEFORT III DISTRACTION SYSTEM

CLEARED

Nov 3, 2003
154 days to decision

K031708 · Product code: **MQN** · Dental
Source: https://www.510kdatabase.net/k031708/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Mandibular Fixator And/or Distractor (MQN)
Date received	Jun 2, 2003
Decision date	Nov 3, 2003
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Osteomed LP**
Location	Addison, TX, US
Contact	DAWN T HOLDERMAN
510(k) history	29 submissions · 29 cleared · 2003-2015