

K013618 INTRAORAL MANDIBULAR DISTRACTION SYSTEM

Aug 14, 2002
282 days to decision

K013618 · Product code: **MQN** · Dental
Source: <https://www.510kdatabase.net/k013618/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Mandibular Fixator And/or Distractor (MQN)
Date received	Nov 5, 2001
Decision date	Aug 14, 2002
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Osteomed Corp.
Location	Glendale, CA, US
Contact	DAWN T HOLDEMAN
510(k) history	27 submissions · 26 cleared · 1991-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k013618/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026