

K080153 SYNTHES (USA) CURVILINEAR DISTRACTION SYSTEM

May 14, 2008
112 days to decision

K080153 · Product code: **MQN** · Dental
Source: <https://www.510kdatabase.net/k080153/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Mandibular Fixator And/or Distractor (MQN)
Date received	Jan 23, 2008
Decision date	May 14, 2008
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synthes (Usa)
Location	Mchenry, IL, US
Contact	ANDREA M TASKER
510(k) history	411 submissions · 394 cleared · 1977-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k080153/> 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 14, 2026