FDA 510(k) Premarket Notification

K080153 SYNTHES (USA) CURVILINEAR DISTRACTION SYSTEM

CLEARED

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