

**K183113 DePuy Synthes Maxillofacial Portfolio - MR
Conditional**Mar 13, 2019
124 days to decisionK183113 · Product code: **MQN** · Dental
Source: <https://www.510kdatabase.net/k183113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Mandibular Fixator And/or Distractor (MQN)
Date received	Nov 9, 2018
Decision date	Mar 13, 2019
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Synthes USA Products, LLC
Location	West Chester, PA, US
Contact	Rebecca Reiter
510(k) history	60 submissions · 60 cleared · 2010-2022

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