

**K162594 Craniomaxillofacial Distraction System (CMFD)**May 8, 2017  
234 days to decisionK162594 · Product code: **MQN** · Dental  
Source: <https://www.510kdatabase.net/k162594/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Mandibular Fixator And/or Distractor (MQN)
Date received	Sep 16, 2016
Decision date	May 8, 2017
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synthes USA Products, LLC</b>
Location	West Chester, PA, US
Contact	NICHOLAS FOUNTOULAKIS
510(k) history	60 submissions · 60 cleared · 2010-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162594/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026