

K170818 Craniomaxillofacial Distraction System (CMFD)Dec 7, 2017
262 days to decisionK170818 · Product code: **PBJ** · Neurology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cranial Distraction System (PBJ)
Date received	Mar 20, 2017
Decision date	Dec 7, 2017
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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