

K140397 PARALOCK PLATING SYSTEM / TUFFNEK SCREWApr 17, 2014
58 days to decisionK140397 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k140397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 18, 2014
Decision date	Apr 17, 2014
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Paragon 28
Location	Chesterland, OH, US
Contact	KAREN E WARDEN
510(k) history	7 submissions · 7 cleared · 2014-2018

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