

K081401 MAYFIELD MR/X-RAY SKULL CLAMPOct 8, 2008
142 days to decisionK081401 · Product code: **HBL** · Neurology
Source: <https://www.510kdatabase.net/k081401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Holder, Head, Neurosurgical (skull Clamp) (HBL)
Date received	May 19, 2008
Decision date	Oct 8, 2008
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Integra Lifesciences Corp.
Location	Somerville, NJ, US
Contact	HELDER A SOUSA
Website	http://www.integra-ls.com/
510(k) history	29 submissions · 29 cleared · 1999-2019

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