

K103493 HEAD FIATION DEVICE (HFD 100)Mar 11, 2011
102 days to decisionK103493 · Product code: **HBL** · Neurology
Source: <https://www.510kdatabase.net/k103493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holder, Head, Neurosurgical (skull Clamp) (HBL)
Date received	Nov 29, 2010
Decision date	Mar 11, 2011
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imris, Inc.
Location	Rockville, MD, US
Contact	THOMAS M TSKERIS
510(k) history	14 submissions · 14 cleared · 2006-2015

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