

**K151536 SmartTwist MRII Hand Drill, SmartTip MRII Drill bit Kit,  
4.5mm, 6.0mm**

Jul 8, 2015  
30 days to decision

K151536 · Product code: **HBG** · Neurology  
Source: <https://www.510kdatabase.net/k151536/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Drills, Burrs, Trephines & Accessories (manual) (HBG)
Date received	Jun 8, 2015
Decision date	Jul 8, 2015
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mri Interventions, Inc.</b>
Location	Irvine, CA, US
Contact	E F WADDELL
510(k) history	14 submissions · 14 cleared · 2011-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k151536/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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