

K213454 Midas Rex MR8 Depth Stop Attachment, Midas Rex MR8 Depth Stop Tool 2.4mm, Midas Rex MR8 Depth Stop Tool 3.2mm, Midas Rex MR8 Depth Stop Tool 3.2mm Long, Midas Rex MR8 Depth Stop Tool 7.5mmNov 23, 2021
28 days to decisionK213454 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k213454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Oct 26, 2021
Decision date	Nov 23, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Powered Surgical Solutions
Location	Fort Worth, TX, US
Contact	Carrie Eddings
510(k) history	9 submissions · 9 cleared · 2007-2021

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