

**K250374 iBur 3.0mm Diamond Match Head, Distal Bend
(8431-107-030D)**Mar 11, 2025
29 days to decisionK250374 · Product code: **HBE** · Neurology
Source: <https://www.510kdatabase.net/k250374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Drills, Burrs, Trephines & Accessories (simple, Powered) (HBE)
Date received	Feb 10, 2025
Decision date	Mar 11, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	iBur 3.0mm Precision Round, Distal Bend (8431-009-030); iBur 4.0mm Precision Round, Distal Bend (8431-009-040); iBur 2.0mm Diamond Round, Distal Bend (8431-012-020D); iBur 3.0mm Diamond Round, Distal Bend (8431-012-030D); iBur 4.0mm Diamond Round, Distal Bend (8431-012-040D); iBur 3.0mm Coarse Diamond Round, Distal Bend (8431-013-030DC); iBur 4.0mm Coarse Diamond Round, Distal Bend (8431-013-040DC); iBur 5.0mm Coarse Diamond R

APPLICANT

Company	Stryker Instruments
Location	Kalamazoo, MI, US
Contact	Alison Garrad
510(k) history	72 submissions · 72 cleared · 1994-2026

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