

K002181 GDC ULTRASOFT COILAug 11, 2000
23 days to decisionK002181 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k002181/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Jul 19, 2000
Decision date	Aug 11, 2000
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific, Target
Location	Freemont, CA, US
Contact	JAMES LEATHLEY
510(k) history	19 submissions · 19 cleared · 1999-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002181/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026