

K991549 EMBOSPHERE MICROSPHERESApr 26, 2000
359 days to decisionK991549 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k991549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Neurovascular Embolization (HCG)
Date received	May 3, 1999
Decision date	Apr 26, 2000
Days to decision	359 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosphere Medical
Location	Rockland, MA, US
Contact	SHEILA HEMEON-HEYER
510(k) history	2 submissions · 2 cleared · 2000-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991549/> 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 June 30, 2026