

K113822 QUADRASPHERE 30 TO 60Mar 8, 2012
72 days to decisionK113822 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k113822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Dec 27, 2011
Decision date	Mar 8, 2012
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosphere Medical, Inc.
Location	Rockland, MA, US
Contact	LINDA J VARROSO
510(k) history	6 submissions · 6 cleared · 2001-2012

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