

K082348 FIBERNET EMBOLIC PROTECTION SYSTEMNov 18, 2008
95 days to decisionK082348 · Product code: **NTE** · CardiovascularSource: <https://www.510kdatabase.net/k082348/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Aug 15, 2008
Decision date	Nov 18, 2008
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lumen Biomedical, Inc.
Location	Plymouth, MN, US
Contact	MARIA E BRITTLE
510(k) history	5 submissions · 4 cleared · 2006-2011

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