

K082806 SPINNING SPIROS, MODEL CH-2000Apr 6, 2009
194 days to decisionK082806 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k082806/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 24, 2008
Decision date	Apr 6, 2009
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Icu Medical, Inc.
Location	Walker, MI, US
Contact	TRACY BEST
510(k) history	66 submissions · 65 cleared · 1984-2026

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