

**K140318 SOUNDSTAR ECO 8F GULTRASOUND CATHETER,
SOUNDSTAR ECO 8F ULTRASOUND CATHETER**Mar 12, 2014
30 days to decisionK140318 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k140318/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Feb 10, 2014
Decision date	Mar 12, 2014
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosense Webster
Location	Diamond Bar, CA, US
Contact	MARINA GUEVREKIAN
510(k) history	3 submissions · 3 cleared · 2014-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140318/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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