

K162503 Stealth System, Stealth Sensor, Stealth Smart Cable, StealthView Software

Mar 24, 2017
198 days to decision

K162503 · Product code: **DSH** · Cardiovascular
Source: <https://www.510kdatabase.net/k162503/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Magnetic Tape, Medical (DSH)
Date received	Sep 7, 2016
Decision date	Mar 24, 2017
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiac Insight, Inc.
Location	Nordland, WA, US
Contact	Brad Harlow
510(k) history	3 submissions · 3 cleared · 2013-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k162503/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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