

K140036 APTUS HELI-FX GUIDE - 22CM DEFLECTABLE LENGTH

Feb 6, 2014
30 days to decision

K140036 · Product code: **OTD** · Cardiovascular
Source: <https://www.510kdatabase.net/k140036/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endovascular Suturing System (OTD)
Date received	Jan 7, 2014
Decision date	Feb 6, 2014
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary
Other names	APTUS HELI-FX GUIDE - 28CM DEFLECTABLE LENGTH; APTUS HELI-FX APPLIER WITH

APPLICANT

Company	Aptus Endosystems, Inc.
Location	Sunnyvale, CA, US
Contact	BURT GOODSON
510(k) history	4 submissions · 3 cleared · 2011-2014

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k140036/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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