

**K153193 Halo II Ambulatory Infusion System (also with trade names Nimbus II Ambulatory Infusion System, EVAA Ambulatory Infusion System)**

Aug 30, 2016  
301 days to decision

K153193 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k153193/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Pump, Infusion (FRN)
Date received	Nov 3, 2015
Decision date	Aug 30, 2016
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zyno Medical, LLC</b>
Location	Waltham, MA, US
Contact	Mei Zhang
510(k) history	7 submissions · 7 cleared · 2007-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k153193/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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