

**K143556 Fujifilm Double Balloon Endoscopes Models EN-530T and EN-580T**Aug 20, 2015  
248 days to decisionK143556 · Product code: FDA · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k143556/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteroscope And Accessories (FDA)
Date received	Dec 15, 2014
Decision date	Aug 20, 2015
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Medical Systems U.S.A, Inc.</b>
Location	Stamford, CT, US
Contact	MARY MOORE
510(k) history	39 submissions · 39 cleared · 2005-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143556/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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