

**K181020 Cytosponge Cell Collection Device**Aug 16, 2018  
121 days to decisionK181020 · Product code: **EOX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k181020/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophagoscope (flexible Or Rigid) (EOX)
Date received	Apr 17, 2018
Decision date	Aug 16, 2018
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Covidien, LLC</b>
Location	Mansfield, MA, US
Contact	Rachel Silva
510(k) history	88 submissions · 85 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181020/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 30, 2026