

**K140938 OSTOM-I ALERT**Oct 10, 2014  
182 days to decisionK140938 · Product code: **EXB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k140938/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Ostomy (EXB)
Date received	Apr 11, 2014
Decision date	Oct 10, 2014
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>11 Health and Technologies, LLC</b>
Location	Crofton, MD, US
Contact	E J SMITH
510(k) history	1 submissions · 1 cleared · 2014-2014

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