

K181643 SmartBag (SmartPouch)Nov 16, 2018
147 days to decisionK181643 · Product code: **EXB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k181643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Collector, Ostomy (EXB)
Date received	Jun 22, 2018
Decision date	Nov 16, 2018
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	11 Health Technologies Limited
Location	Borehamwood, GB
Contact	Michael Seres
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181643/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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