

K190208 Diversatek Healthcare High Resolution Impedance Manometry (HRiM) ProbeOct 3, 2019
241 days to decisionK190208 · Product code: FFX · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190208/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Feb 4, 2019
Decision date	Oct 3, 2019
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diversatek Healthcare
Location	Highlands Ranch, CO, US
Contact	Laura L. Boll
510(k) history	3 submissions · 3 cleared · 2019-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190208/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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