

K201765 SmarHDM-510 SystemSep 2, 2020
65 days to decisionK201765 · Product code: **FIZ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k201765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Meter, Conductivity, Non-remote (FIZ)
Date received	Jun 29, 2020
Decision date	Sep 2, 2020
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mesa Laboratories, Inc.
Location	Lakewood, CO, US
Contact	Jamie Louie
510(k) history	9 submissions · 9 cleared · 2004-2020

REGULATORY CONSULTANT

Consulting firm	Ibp Medical GmbH
Contact	Johannes Pfingstmann

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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