

K192704 Endofresh Digestive Endoscopy SystemSep 2, 2020
341 days to decisionK192704 · Product code: **FDS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k192704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Sep 27, 2019
Decision date	Sep 2, 2020
Days to decision	341 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Huizhou Xzing Technology Co., Ltd.
Location	Huizhou, CN
Contact	Yonglin Ni
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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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