

K202616 ClearCap Distal AttachmentFeb 19, 2021
163 days to decisionK202616 · Product code: **OCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k202616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Irrigation/suction System (OCX)
Date received	Sep 9, 2020
Decision date	Feb 19, 2021
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Finemedix Co., Ltd.
Location	Daegu, KR
Contact	Seok-Jun Ma
510(k) history	11 submissions · 11 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	Withus Group, Inc.
Contact	April Lee

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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