FDA 510(k) Premarket Notification

K210137 EsoCheck Cell Collection Device

CLEARED

Feb 18, 2021
30 days to decision

K210137 · Product code: **EOX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k210137/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Special
Device classification	Esophagoscope (flexible Or Rigid) (EOX)
Date received	Jan 19, 2021
Decision date	Feb 18, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lucid Diagnostics, Inc.**
Location	New York, NY, US
Contact	Lishan Aklog
510(k) history	4 submissions · 0 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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