FDA 510(k) Premarket Notification

K211326 EndoScreener

CLEARED

Nov 19, 2021
203 days to decision

K211326 · Product code: **QNP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k211326/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointesinal Lesion Software Detection System (QNP)
Date received	Apr 30, 2021
Decision date	Nov 19, 2021
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Chengdu Wision Medical Device Co., Ltd.**
Location	Chengdu, CN
Contact	JingJia Liu
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John J Smith

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