

K211326 EndoScreenerNov 19, 2021
203 days to decisionK211326 · Product code: **QNP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k211326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211326/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026