

**K203350 ENDOtube**Sep 29, 2021  
320 days to decisionK203350 · Product code: **OCX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k203350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Irrigation/suction System (OCX)
Date received	Nov 13, 2020
Decision date	Sep 29, 2021
Days to decision	320 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nissha Medical Technologies Sas</b>
Location	Conflans Ste Honorine, FR
Contact	Roch Mignot
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203350/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026