

K150927 Orchestra Hydrophilic Guidewire standard angled, Orchestra Hydrophilic Guidewire straight stiff, Orchestra Hydrophilic Guidewire angled stiff, Orchestra Hydrophilic Guidewire standard straight, Orchestra Hydrophilic Guidewire straight stiffMay 27, 2015
51 days to decisionK150927 · Product code: **OCY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k150927/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Guidewire, Gastroenterology-urology (OCY)
Date received	Apr 6, 2015
Decision date	May 27, 2015
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast A/S
Location	Mchenry, IL, US
Contact	LEEANNE SWIRIDOW
Website	http://www.coloplast.com/
510(k) history	71 submissions · 68 cleared · 1983-2023

Coloplast A/S is a Danish multinational medical device manufacturer based in McHenry, US. The company develops and markets devices for ostomy, urology, continence, and wound care. Coloplast has received FDA 510(k) clearances from total submissions since its first clearance in 1983. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including catheter systems, guidewires, and access sheaths. The latest clearance on record dates to 2023, reflecting the company's historical engagement with FDA regulatory pathways. Notable cleared devices i...

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