

K112477 PALINDROME H, SI, HSI CHRONIC CATHETERSep 28, 2011
30 days to decisionK112477 · Product code: **NYU** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k112477/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Special
Device classification	Catheter, Hemodialysis, Implanted, Coated (NYU)
Date received	Aug 29, 2011
Decision date	Sep 28, 2011
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien
Location	North Haven, CT, US
Contact	WING NG
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...

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Device record: <https://www.510kdatabase.net/k112477/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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