

K153461 Guide wire for Edi Catheter 6 Fr, Guide wire for Edi Catheter 8 Fr, 100 cm, Guide wire for Edi Catheter 8 Fr, 125 cm

Dec 11, 2015
10 days to decision

K153461 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k153461/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Dec 1, 2015
Decision date	Dec 11, 2015
Days to decision	10 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Maquet Critical Care AB
Location	Iselin, NJ, US
Contact	Mirva Boothe
510(k) history	19 submissions · 19 cleared · 2004-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k153461/> 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 27, 2026