

K183219 Trio-CT Triple Lumen CatheterJun 14, 2019
206 days to decisionK183219 · Product code: **NIE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k183219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Triple Lumen, Non-implanted (NIE)
Date received	Nov 20, 2018
Decision date	Jun 14, 2019
Days to decision	206 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medical Components, Inc. (dba MedComp)
Location	Harleysville, PA, US
Contact	Courtney Nix
510(k) history	9 submissions · 5 cleared · 2017-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183219/> 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