FDA 510(k) Premarket Notification

K183219 Trio-CT Triple Lumen Catheter

CLEARED

Jun 14, 2019
206 days to decision

K183219 · 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