FDA 510(k) Premarket Notification

CLEARED

K023023 LIFESITE HEMODIALYSIS ACCESS SYSTEM, CANNULA EXCHANGE KIT, INSERTION KIT, ACCESS CANNILA

Dec 4, 2003
449 days to decision

K023023 · Product code: **MSD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k023023/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Implanted (MSD)
Date received	Sep 11, 2002
Decision date	Dec 4, 2003
Days to decision	449 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vasca, Inc.**
Location	Tewksburt, MA, US
Contact	NAMA DODDI
510(k) history	2 submissions · 2 cleared · 2000-2003