FDA 510(k) Premarket Notification

K180552 Modified Novy Cornual Cannulation Set

CLEARED

Jul 12, 2018
133 days to decision

K180552 · Product code: **MOV** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k180552/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheters, Salpingography (MOV)
Date received	Mar 1, 2018
Decision date	Jul 12, 2018
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cook Incorporated**
Location	Bloomington, IN, US
Contact	Naomi Funkhouser
510(k) history	175 submissions · 153 cleared · 2006-2024