FDA 510(k) Premarket Notification

CLEARED

K181757 Günther Tulip® Vena Cava Filter Retrieval Set

Nov 6, 2018
127 days to decision

K181757 · Product code: **MMX** · Cardiovascular
Source: https://www.510kdatabase.net/k181757/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Percutaneous Retrieval (MMX)
Date received	Jul 2, 2018
Decision date	Nov 6, 2018
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Cook Research Incorporated**
Contact	Jennifer Brown

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov