FDA 510(k) Premarket Notification

K081410 OPTION VENA CAVA FILTER

CLEARED

Jun 4, 2009
380 days to decision

K081410 · Product code: **DTK** · Cardiovascular
Source: https://www.510kdatabase.net/k081410/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Intravascular, Cardiovascular (DTK)
Date received	May 20, 2008
Decision date	Jun 4, 2009
Days to decision	380 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rex Medical**
Location	Great Neck, NY, US
Contact	LEO BASTA
510(k) history	13 submissions · 11 cleared · 2003-2012