FDA 510(k) Premarket Notification

K120857 EPI-SENSE GUIDED COAGULATION DEVICE WITH VISITRAX

CLEARED

Nov 13, 2012
237 days to decision

K120857 · Product code: **OCL** · Cardiovascular
Source: https://www.510kdatabase.net/k120857/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Device, For Cutting, Coagulation, And/or Ablation Of Tissue, Including Cardiac Tissue (OCL)
Date received	Mar 21, 2012
Decision date	Nov 13, 2012
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ncontact Surgical, Inc.**
Location	Morrisville, NC, US
Contact	JANE RICUPERO
510(k) history	7 submissions · 7 cleared · 2006-2014