

K161218 Gianturco-Roehm Bird's Nest Vena Cava FilterJul 22, 2016
84 days to decisionK161218 · Product code: **DTK** · Cardiovascular
Source: <https://www.510kdatabase.net/k161218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Intravascular, Cardiovascular (DTK)
Date received	Apr 29, 2016
Decision date	Jul 22, 2016
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161218/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026