

K163031 Bunegin-Albin Air Aspiration SetJul 27, 2017
269 days to decisionK163031 · Product code: **DXE** · Cardiovascular
Source: <https://www.510kdatabase.net/k163031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Oct 31, 2016
Decision date	Jul 27, 2017
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163031/> 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 1, 2026