FDA 510(k) Premarket Notification

K030504 AKONYA ELIMINATOR MECHANICAL THROMBECTOMY DEVICE, MODEL EL 10060060

CLEARED

Sep 16, 2003
209 days to decision

K030504 · Product code: **MCW** · Cardiovascular
Source: https://www.510kdatabase.net/k030504/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Feb 19, 2003
Decision date	Sep 16, 2003
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Idev Technologies, Inc.**
Location	Houston, TX, US
Contact	LYNNE A DAVIES
510(k) history	11 submissions · 4 cleared · 2003-2013