FDA 510(k) Premarket Notification

K963595 SERAGARD VASCULAR ACCESS DEVICE

CLEARED

Jan 6, 1997
119 days to decision

K963595 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k963595/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 9, 1996
Decision date	Jan 6, 1997
Days to decision	119 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Cutting Edge Technologies, Inc.**
Location	Malvern, PA, US
Contact	WALTER L YATES
510(k) history	2 submissions · 2 cleared · 1995-1997