FDA 510(k) Premarket Notification

K880162 PLEUR-EVAC--A-5002 CHEST DRAINAGE SYSTEM W/AUTO

CLEARED

Mar 21, 1988
68 days to decision

K880162 · Product code: **CAC** · Anesthesiology
Source: https://www.510kdatabase.net/k880162/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Jan 13, 1988
Decision date	Mar 21, 1988
Days to decision	68 days
Third-party review	No

APPLICANT

Company	**Deknatel, Inc.**
Location	Fall River, MA, US
Contact	RICHARD J LARKIN
Website	https://www.teleflex.com
510(k) history	37 submissions · 37 cleared · 1976-1997

Deknatel, Inc. is a medical device manufacturer based in Fall River, US. The company specializes in surgical devices and wound closure solutions. Deknatel received FDA 510(k) clearances from total submissions between 1976 and 1997. The company's cleared devices span multiple surgical specialties, with particular strength in anesthesiology and general surgery. Notable product lines include autotransfusion systems, chest drainage devices, and surgical sutures in various materials and configurations. The company is inactive and represents a historical regulatory record. No F...