FDA 510(k) Premarket Notification

K882223 PLEUR-EVAC-A-7000--ADULT/PEDI CHEST DRAINAGE SYST

CLEARED

Aug 16, 1988
82 days to decision

K882223 · Product code: **KDQ** · General Hospital
Source: https://www.510kdatabase.net/k882223/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bottle, Collection, Vacuum (KDQ)
Date received	May 26, 1988
Decision date	Aug 16, 1988
Days to decision	82 days
Third-party review	No

APPLICANT

Company	**Deknatel, Inc.**
Location	Fall River, MA, US
Contact	BETTY OROFINO
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...