FDA 510(k) Premarket Notification

K905768 PLEUR-EVAC CHEST DRAINAGE SYSTEMS

CLEARED

Feb 11, 1991
46 days to decision

K905768 · Product code: **KDQ** · General Hospital
Source: https://www.510kdatabase.net/k905768/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bottle, Collection, Vacuum (KDQ)
Date received	Dec 27, 1990
Decision date	Feb 11, 1991
Days to decision	46 days
Third-party review	No

APPLICANT

Company	**Deknatel, Inc.**
Location	Fall River, MA, US
Contact	MICHAEL SANTALUCIA
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...