FDA 510(k) Premarket Notification

K862524 DEKNATEL (R) TREPHINE

CLEARED

Aug 11, 1986
40 days to decision

K862524 · Product code: **HRH** · Ophthalmic
Source: https://www.510kdatabase.net/k862524/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trephine, Manual, Ophthalmic (HRH)
Date received	Jul 2, 1986
Decision date	Aug 11, 1986
Days to decision	40 days
Third-party review	No

APPLICANT

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