FDA 510(k) Premarket Notification

CLEARED

K911905 DEKNATEL(R) MICROFLEX OPHTHAL POLY SUTURE,MODIFIED

Jul 2, 1991
74 days to decision

K911905 · Product code: **GAW** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k911905/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polypropylene (GAW)
Date received	Apr 19, 1991
Decision date	Jul 2, 1991
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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