FDA 510(k) Premarket Notification

K920409 DACOMED BATTERY OPERATED VACUUM ERECTION DEVICE

CLEARED

May 11, 1992
101 days to decision

K920409 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k920409/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Jan 31, 1992
Decision date	May 11, 1992
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dacomed Corp.**
Location	Mchenry, IL, US
Contact	MARY M WILEN
510(k) history	20 submissions · 20 cleared · 1981-1995