FDA 510(k) Premarket Notification

K905195 FIRM MASTER

CLEARED

Feb 1, 1991
74 days to decision

K905195 · Product code: **LKY** · Toxicology
Source: https://www.510kdatabase.net/k905195/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Nov 19, 1990
Decision date	Feb 1, 1991
Days to decision	74 days
Third-party review	No

APPLICANT

Company	**Bak Medical Products**
Location	Martinez, CA, US
Contact	DANIEL MERRILL
510(k) history	1 submissions · 1 cleared · 1991-1991