FDA 510(k) Premarket Notification

K820053 KERLIX FLUFFS

CLEARED

Feb 4, 1982
24 days to decision

K820053 · Product code: **NAB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k820053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze / Sponge,nonresorbable For External Use (NAB)
Date received	Jan 11, 1982
Decision date	Feb 4, 1982
Days to decision	24 days
Third-party review	No

APPLICANT

Company	**Stan-Pak Ent.**
Location	Mchenry, IL, US
510(k) history	20 submissions · 20 cleared · 1982-1982