FDA 510(k) Premarket Notification

K974480 SILIMED CALF IMPLANT

CLEARED

Feb 24, 1998
90 days to decision

K974480 · Product code: **MIB** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k974480/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone Block (MIB)
Date received	Nov 26, 1997
Decision date	Feb 24, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Silimed, LLC**
Location	Crofton, MD, US
Contact	E J SMITH
510(k) history	9 submissions · 9 cleared · 1998-1998

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k974480/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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