FDA 510(k) Premarket Notification

K053655 TENDON WRAP TENDON PROTECTOR

CLEARED

Feb 3, 2006
35 days to decision

K053655 · Product code: **FTM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k053655/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Dec 30, 2005
Decision date	Feb 3, 2006
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Integra LifeSciences Corporation**
Location	Planisboro, NJ, US
Contact	DIANA M BORDON
510(k) history	65 submissions · 65 cleared · 2004-2025