FDA 510(k) Premarket Notification

K213512 DERMABOND PRINEO Skin Closure System

CLEARED

Dec 7, 2021
35 days to decision

K213512 · Product code: **OMD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213512/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cutaneous Tissue Adhesive With Mesh (OMD)
Date received	Nov 2, 2021
Decision date	Dec 7, 2021
Days to decision	35 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ethicon, Inc.**
Location	Raritan, NJ, US
Contact	Noorhidayah Norizan
Website	https://www.jnjmedtech.com
510(k) history	203 submissions · 196 cleared · 1976-2026

Ethicon, Inc. is a subsidiary of Johnson & Johnson specializing in surgical sutures and wound closure devices. The company is headquartered in Raritan, United States. Ethicon has received FDA 510(k) clearances from total submissions since 1976. The company's regulatory focus centers on General & Plastic Surgery devices, which represent the majority of its cleared submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued regulatory activity. Ethicon has manufactured surgical sutures and wound closure technologies since 1887. The company hold...