FDA 510(k) Premarket Notification

K963950 BIODERM EID MALE EXTERNAL INCONTINENCE DEVICE

CLEARED

Jan 10, 1997
100 days to decision

K963950 · Product code: **EXI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k963950/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Paste-on For Incontinence, Sterile (EXI)
Date received	Oct 2, 1996
Decision date	Jan 10, 1997
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bioderm, Inc.**
Location	Wheaton, IL, US
Contact	ERIC FLAM
510(k) history	14 submissions · 10 cleared · 1987-1999