FDA 510(k) Premarket Notification

K912736 ERECAID(R) SYSTEM PLUS

CLEARED

Aug 12, 1991
52 days to decision

K912736 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k912736/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, External Penile Rigidity (LKY)
Date received	Jun 21, 1991
Decision date	Aug 12, 1991
Days to decision	52 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Osbon Medical Systems, Ltd.**
Location	Augusta, GA, US
Contact	JULIAN W OSBON
510(k) history	4 submissions · 4 cleared · 1989-1991

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k912736/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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