FDA 510(k) Premarket Notification

K020082 ERECAID CLASSIC SYSTEM

CLEARED

Feb 5, 2002
26 days to decision

K020082 · Product code: **LKY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k020082/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, External Penile Rigidity (LKY)
Date received	Jan 10, 2002
Decision date	Feb 5, 2002
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary
Other names	ERECAID ESTEEM MANUAL SYSTEM; ERECAID ESTEEM BATTERY SYSTEM

APPLICANT

Company	**Endocare, Inc.**
Location	Irvine, CA, US
Contact	CHRIS HADLAND
Website	http://www.endocare.com/
510(k) history	22 submissions · 22 cleared · 1996-2010