FDA 510(k) Premarket Notification

K955810 U-TEX

CLEARED

Jan 24, 1996
29 days to decision

K955810 · Product code: **FHA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k955810/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Penile (FHA)
Date received	Dec 26, 1995
Decision date	Jan 24, 1996
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Laborie Medical Technologies, Ltd.**
Location	North Attleboro, MA, US
Contact	FRED BUFFA
510(k) history	11 submissions · 11 cleared · 1992-2009