

K955810 U-TEXJan 24, 1996
29 days to decisionK955810 · Product code: **FHA** · Gastroenterology & UrologySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955810/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 22, 2026