

K885323 DACOMED EXTERNAL MALE CONTINENCE DEVICEFeb 8, 1989
42 days to decisionK885323 · Product code: **FHA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k885323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Penile (FHA)
Date received	Dec 28, 1988
Decision date	Feb 8, 1989
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Dacomed Corp.
Location	Mchenry, IL, US
Contact	MARY M WILEN
510(k) history	20 submissions · 20 cleared · 1981-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k885323/>; 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 July 1, 2026