

K850019 OMNI PHASE PENILE PROSTHESISApr 9, 1985
96 days to decisionK850019 · Product code: **FAE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k850019/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Jan 3, 1985
Decision date	Apr 9, 1985
Days to decision	96 days
Third-party review	No

APPLICANT

Company	Dacomed Corp.
Location	Mchenry, IL, US
Contact	FRANK B FREEDMAN
510(k) history	20 submissions · 20 cleared · 1981-1995

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