

K953640 DUNA II PENILE PROSTHESISOct 27, 1995
84 days to decisionK953640 · Product code: **FAE** · Gastroenterology & Urology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Aug 4, 1995
Decision date	Oct 27, 1995
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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