

**K834347 FLEXI-FLATE PENILE IMPLANT**Apr 2, 1984  
111 days to decisionK834347 · Product code: **FAE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k834347/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Penile (FAE)
Date received	Dec 13, 1983
Decision date	Apr 2, 1984
Days to decision	111 days
Third-party review	No

**APPLICANT**

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Company	<b>Surgitek</b>
Location	Mchenry, IL, US
510(k) history	29 submissions · 28 cleared · 1983-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k834347/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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