

**K963064 ANO-RECTAL MANOMETRY OPTION, MODEL  
NUMBER UDS-ARM**Jun 5, 1997  
302 days to decisionK963064 · Product code: FFX · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k963064/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Aug 7, 1996
Decision date	Jun 5, 1997
Days to decision	302 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Laborie Medical Tech Corp.</b>
Location	Mississauga, CA
Contact	THOMAS HIRTE
510(k) history	5 submissions · 5 cleared · 1995-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963064/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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