

**K760127 TRAY, CATHETERIZATION W/O CATHETER**Oct 7, 1976  
101 days to decisionK760127 · Product code: **FCM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k760127/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Jun 28, 1976
Decision date	Oct 7, 1976
Days to decision	101 days
Third-party review	No

**APPLICANT**

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Company	<b>Concord Laboratories, Inc.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.concordlabs.com">https://www.concordlabs.com</a>
510(k) history	42 submissions · 38 cleared · 1976-1989

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k760127/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026