FDA 510(k) Premarket Notification

K940203 TRIPLE LUMEN URODYNAMIC CATHETER WITH RADIOPAQUE MARKERS

CLEARED

Mar 30, 1994
76 days to decision

K940203 · Product code: **FEN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k940203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Cystometric, Hydraulic (FEN)
Date received	Jan 13, 1994
Decision date	Mar 30, 1994
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Life-Tech Intl., Inc.**
Location	Walker, MI, US
Contact	ALFRED C COATS
510(k) history	68 submissions · 66 cleared · 1982-2000

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k940203/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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