

K823561 URETHRAL PRESSURE PROFILE & TEMP. MODULJan 7, 1983
36 days to decisionK823561 · Product code: **FAP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k823561/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP)
Date received	Dec 2, 1982
Decision date	Jan 7, 1983
Days to decision	36 days
Third-party review	No

APPLICANT

Company	Nihon Kohden America, Inc.
Location	Foothill Ranch, CA, US
510(k) history	166 submissions · 163 cleared · 1979-2012

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k823561/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026