FDA 510(k) Premarket Notification

K823561 URETHRAL PRESSURE PROFILE & TEMP. MODUL

CLEARED

Jan 7, 1983
36 days to decision

K823561 · Product code: **FAP** · Gastroenterology & Urology
Source: 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