FDA 510(k) Premarket Notification

K000135 PRO.DUCT CATHETER, MODEL CTH03

CLEARED

Apr 10, 2000
83 days to decision

K000135 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k000135/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Jan 18, 2000
Decision date	Apr 10, 2000
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pro. Duct Health, Inc.**
Location	Menlo Park, CA, US
Contact	ANGELA B SOITO
510(k) history	2 submissions · 2 cleared · 2000-2000