FDA 510(k) Premarket Notification

K030662 PATHWAY ACCESS SHEATH CATHETER

CLEARED

Sep 3, 2003
184 days to decision

K030662 · Product code: **EZN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k030662/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Mar 3, 2003
Decision date	Sep 3, 2003
Days to decision	184 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Vertelink Corporation**
Location	Mission Viejo, CA, US
Contact	ALBERT REGO
510(k) history	3 submissions · 3 cleared · 2003-2003