FDA 510(k) Premarket Notification

K110214 DIRECTVISION CATHETER, UNCOATED

CLEARED

May 27, 2011
122 days to decision

K110214 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k110214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jan 25, 2011
Decision date	May 27, 2011
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Percuvision**
Location	Ashland, MA, US
Contact	FIDES MALDONADO
510(k) history	1 submissions · 1 cleared · 2011-2011