FDA 510(k) Premarket Notification

K090262 PERCUCATH URINARY CATHETER

CLEARED

May 28, 2009
114 days to decision

K090262 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k090262/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Feb 3, 2009
Decision date	May 28, 2009
Days to decision	114 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Percuvision, LLC**
Location	Gahanna, OH, US
Contact	ERROL SINGH
510(k) history	2 submissions · 2 cleared · 2009-2009