

**K043254 PATHWAY URETERAL ACCESS SHEATH, PATHWAY
EXPANDABLE URETERAL ACCESS SHEATH**Feb 10, 2005
78 days to decisionK043254 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k043254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Nov 24, 2004
Decision date	Feb 10, 2005
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Onset Medical Corporation
Location	Mission Viejo, CA, US
Contact	ALBERT REGO
510(k) history	8 submissions · 8 cleared · 2005-2016

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