

**K132181 GYRUS ACMI URO-EZDILATE URETERAL BALLOON
DILATION CATHETER**Oct 21, 2013
98 days to decisionK132181 · Product code: **EZN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k132181/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Catheter, Ureteral (EZN)
Date received	Jul 15, 2013
Decision date	Oct 21, 2013
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Surgical Technologies America
Location	Southborough, MA, US
Contact	NEIL KELLY
510(k) history	12 submissions · 12 cleared · 2012-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132181/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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