

K191061 Optilume Basic Urological Balloon Dilation CatheterJan 2, 2020
255 days to decisionK191061 · Product code: **KOE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k191061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Urethral (KOE)
Date received	Apr 22, 2019
Decision date	Jan 2, 2020
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Urotronic, Inc.
Location	Minneapolis, MN, US
Contact	David Perry
510(k) history	2 submissions · 2 cleared · 2020-2025

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