

**K191264 Every Second Matters-Uterine Balloon Tamponade
("ESM-UBT")**Oct 30, 2019
173 days to decisionK191264 · Product code: **OQY** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k191264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intrauterine Tamponade Balloon (OQY)
Date received	May 10, 2019
Decision date	Oct 30, 2019
Days to decision	173 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ujenzi Charitable Trust
Location	Medford, MA, US
Contact	Thomas Burke
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Jonathan S. Kahan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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