

K173657 Radiance(TM) Clear Sharklet(R) Silicone Foley CatheterAug 23, 2018
267 days to decisionK173657 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k173657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Nov 29, 2017
Decision date	Aug 23, 2018
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Samuel Engelman
510(k) history	175 submissions · 153 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173657/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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