

K190492 Peralta Stone Removal CatheterJul 18, 2019
140 days to decisionK190492 · Product code: **FFL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190492/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dislodger, Stone, Basket, Ureteral, Metal (FFL)
Date received	Feb 28, 2019
Decision date	Jul 18, 2019
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Calcula Technologies, Inc.
Location	San Francisco, CA, US
Contact	Raymond Buzz Bonneau
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Allison Komiyama

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190492/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026