

K191438 ERBEFLO 2 Endo Quick Connect Pentax Scope Port Connector

Jun 27, 2019
28 days to decision

K191438 · Product code: **OCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191438/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Irrigation/suction System (OCX)
Date received	May 30, 2019
Decision date	Jun 27, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Erbe USA, Inc.
Location	Lawrenceville, GA, US
Contact	John Tartal
510(k) history	39 submissions · 39 cleared · 1994-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k191438/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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