

K193036 C2 CryoBalloon EndoGripNov 22, 2019
22 days to decisionK193036 · Product code: **OCX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Irrigation/suction System (OCX)
Date received	Oct 31, 2019
Decision date	Nov 22, 2019
Days to decision	22 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pentax Medical, A Division of Pentax of America, Inc.
Location	Redwood, Ca, CA, US
Contact	Gurvinder Singh Nanda
510(k) history	2 submissions · 2 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193036/> 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 28, 2026