

K191020 G210 InviCell Plus with SignipHy pH monitoringJan 14, 2020
272 days to decisionK191020 · Product code: **PUB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k191020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory, Assisted Reproduction, Exempt (PUB)
Date received	Apr 17, 2019
Decision date	Jan 14, 2020
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CooperSurgical, Inc.
Location	Mountain View, CA, US
Contact	Kyle Hooper
510(k) history	41 submissions · 40 cleared · 1991-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191020/> 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 May 14, 2026