FDA 510(k) Premarket Notification

CLEARED

K191020 G210 InviCell Plus with SignipHy pH monitoring

Jan 14, 2020
272 days to decision

K191020 · Product code: **PUB** · Obstetrics & Gynecology
Source: 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