

K193361 ProCell Surgical Sponge-Blood Recovery UnitJun 1, 2020
180 days to decisionK193361 · Product code: **CAC** · Cardiovascular
Source: <https://www.510kdatabase.net/k193361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Dec 4, 2019
Decision date	Jun 1, 2020
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Procell Surgical, Inc.
Location	Toronto, CA
Contact	Robert Krensky
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	MEDlcept, Inc.
Contact	Sharyn Orton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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