FDA 510(k) Premarket Notification

K193361 ProCell Surgical Sponge-Blood Recovery Unit

CLEARED

Jun 1, 2020
180 days to decision

K193361 · 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	**MEDIcept, Inc.**
Contact	Sharyn Orton

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