

K183205 PureBMC SupraPhysiologic Concentrating System 30 mL System, PureBMC SupraPhysiologic Concentrating System 60 mL System, PureBMC SupraPhysiologic Concentrating System 120 mL System

May 30, 2019
192 days to decision

K183205 · Product code: **JQC** · Hematology
Source: <https://www.510kdatabase.net/k183205/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Centrifuges (micro, Ultra, Refrigerated) For Clinical Use (JQC)
Date received	Nov 19, 2018
Decision date	May 30, 2019
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Emcyte Corporation
Location	Fort Meyers, FL, US
Contact	Patrick Pennie
510(k) history	2 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183205/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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