Approval Order
November 24, 2020

Cerus Corporation
Attention: Ms. Carol M. Moore
1220 Concord Avenue, Suite 600
Concord, CA 94520

Re: BP130076/34
Trade Name: INTERCEPT® Blood System for Plasma
Product Code: PJF
Filed: May 29, 2020
Amended: June 26, 2020; July 10; 2020; July 17, 2020; August 21, 2020, September 1, 2020, September 9, 2020; September 18, 2020; September 29, 2020; October 5, 2020; October 15, 2020; October 16, 2020; October 22, 2020; November 2, 2020; November 23, 2020

Dear Ms. Moore:

The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) 180-day supplement. You requested approval for the processing container (INTERCEPT Blood System for Cryoprecipitation) for use with the INTERCEPT Processing Set for plasma to produce Pathogen Reduced Cryoprecipitated Fibrinogen Complex, and Pathogen Reduced Plasma, Cryoprecipitate Reduced. The storage time of blood components prepared from this system is as follows :

1. Pathogen Reduced Cryoprecipitated Fibrinogen Complex (single or pooled), stored at or below -18 °C (-0.4 °F) for up to 12 months and upon thawing, at (b) (4) for up to (b) (4).

2. Pathogen Reduced Plasma, Cryoprecipitate Reduced, stored at or below -18 °C (-0.4 °F) for up to 12 months and upon thawing, at 1 °C to 6 °C for up to 5 days.

Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

Expiration dating for the INTERCEPT Cryoprecipitate Processing Container (ICPC) has been established and approved at 6 months. To request extension of dating beyond 6 months, please submit supporting information as a Real-Time PMA Supplement, according to section 737(4)(D) of the Federal Food, Drug, and Cosmetic Act.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as **"Annual Report"** and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or

otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product postmarketing safety reporting is available at (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CBER does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit a Product Correspondence to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, **unless otherwise specified** (**Please see Note below**), to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please Note:
In response to the COVID-19 public health emergency, CBER's Document Control Center (DCC) will not process any submission received by mail or courier including submissions provided on paper and electronic media (e.g., CDs, USB) until further notice. Device submissions, for CBER regulated devices, can still be submitted electronically using the Electronic Submissions Gateway (ESG) (under 10GB) or in some cases via email (under 150MB) in accordance with final industry guidance, eCOPY Program for Medical Devices Submissions found at https://www.fda.gov/media/83522/download. CBER strongly encourages sending submissions through the ESG, FDA's preferred secure method of transmission. Instructions for setting up an ESG account can be found at https://www.fda.gov/industry/electronic-submissions-gateway.

Submissions regarding this file may also be submitted electronically via email at CBERDCC_eMailSub@fda.hhs.gov. We will accept submissions through this email option only during the COVID-19 public health emergency. For additional information regarding CBER operations during this public health emergency, please see the CBER COVID -19 CBER Regulated Biologics page found at https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics.

If you have any questions concerning this approval order, please contact Cherry Geronimo, RPMS Team Lead, at (240) 402-9555 or Cherry.Geronimo@fda.hhs.gov.

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research