DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 10, 2022

Cindy Katsempris
B|Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109

Sent via email to: Nicole.vaitekonis@bbraunusa.com

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug Administration to determine that Heparin Sodium in Sodium Chloride Injection in Plastic Container products listed below, approved under NDA 019802, held by B. Braun Medical Inc., were not withdrawn from marketing for safety or effectiveness reasons was received and processed under CFR 10.30 by this office on 01/10/2022.

It was assigned docket number FDA-2022-P-0060. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-Bigby
Digitally signed by Dynna Gorham-Bigby
Date: 2022.01.11 12:49:39 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)