DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180843

Device Name
HIgH-Flo Super26™ Subcutaneous Needle Sets

Indications for Use *(Describe)*
RMS High-FLO Super26™ Subcutaneous Needle Sets are indicated for subcutaneous infusion of medications in the home, hospital, or ambulatory settings when administered according to the approved biologic or drug product labeling for the capacity for infusion of high flow rates including human plasma-derived immunoglobulins when used according to the FDA approved biologic labeling for: Hizentra®, Immune Globulin Subcutaneous (Human) 20% Liquid (manufactured by CSL Behring); and Cuvitru™ Immune Globulin Infusion (Human) 20% (manufactured by Shire).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."