October 4, 2019

Prapela, Inc.
℅ Sugato De
Vice President - Technical
Parexel International
4600 East-West Highway, Suite 350
Bethesda, Maryland 20814

Re: Q191591
Trade/Device Name: Prapela SVS Hospital Bassinet Pad
Received: August 8, 2019

Dear Sugato De:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received the above submission requesting designation as a Breakthrough Device. The proposed indications for use include "The Prapela SVS Hospital Bassinet Pad is indicated as an adjunctive therapy to concurrent pharmacological treatment for the reduction of irritability and improvement of normal breathing and heart rate in newborns with prenatal opioid exposure and/or diagnosed with neonatal abstinence syndrome (NAS)." We are pleased to inform you that your device and proposed indication for use meet the criteria and have been granted designation as a Breakthrough Device. Please refer to the FDA guidance document entitled "Breakthrough Devices Program", for more information regarding the program, available at https://www.fda.gov/media/108135/download.

We recommend you review the FDA guidance document for the Breakthrough Devices Program referenced above for the available mechanisms for obtaining feedback from the Agency on device development for designated breakthrough devices. When submitting any new requests, please reference Q191591. Any new submission should include two copies (one hardcopy and a valid ecopy), the FDA reference number for this submission, and should be submitted to the following address:

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

You are reminded that as specified in Section 515B(g)(1) of the Federal Food, Drug, and Cosmetic Act, a Breakthrough Device Designation does not change the requirements for approval of an application for an Investigational Device Exemption under section 520(g) or marketing authorizations under section 515(c), 510(k), or 513(f)(2) of the Food, Drug, and Cosmetic Act. Additionally, the information used to support a

premarket submission for a Breakthrough Device must meet the requirements of valid scientific evidence (21 CFR 860.7). You are further advised that the granting of a Breakthrough Device Designation does not guarantee that the application will ultimately be approved.

If you have any questions, please contact Keith Marin at 301-796-2462 or Keith.Marin@fda.hhs.gov.

Sincerely,

Tina Kiang -S

for Benjamin R. Fisher, Ph.D.
Director
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health