December 20, 2022

Medcura
Nancy Lince
Regulatory Affairs Consultant for Medcura, Inc; President & CEO
5650 Rivertech Court
Suite S
Riverdale, Maryland 20737

Re: Q212426/S001
Trade/Device Name: LifeGel
Received: November 30, 2022

Dear Nancy Lince:

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 includes "LifeGel is indicated in surgical procedures (except in ophthalmic and urological) as an adjunctive hemostatic device when control of minimal, mild, and moderate bleeding by conventional procedures is ineffective or impractical. Due to its no-swell properties, LifeGel can be used in surgical procedures where swelling cannot be tolerated." 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 have determined that your device qualifies for designation as a Breakthrough Device, but we have not yet reviewed your provided Data Development Plan (DDP) or any request for feedback. To receive feedback on your Data Development Plan and/or responses to any provided questions, please make this request for feedback under a supplement to this Q-submission. As part of your request, you may reference material already submitted in this Q-submission, as applicable, rather than resubmitting the same material.

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 Q212426/S001. Any new submission should be provided as an eCopy, it should include 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 contac[redacted]@fda.hhs.gov.

Sincerely,

[redacted]

for [redacted] Ph.D.
Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health