Re: C200046
Product Name: SDS Blocker CL-40 Dated: April 7, 2020
Received: April 13, 2020

September 1, 2020

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the
SDS Blocker CL-40. In the submission, you claimed that your product is a general wellness product. The general wellness products should meet two factors as defined in the FDA guidance document, General Wellness: Policy for Low Risk Devices Guidance for Industry and Food and Drug Administration Staff, issued September 27, 2019: (1) are intended for only general wellness use, and (2) present a low risk to the safety of users and other persons. You state that your product SDS Blocker CL-40 acts as a sanitizer and deodorizer by releasing chlorine dioxide to kill odors, pollen, viruses, bacteria and germs. It is not intended for general wellness use and the close proximity of toxic chlorine dioxide to the wearer may present significant risks through inhalation and dermal exposure. Therefore, the SDS Blocker CL-40 does not fall under the general wellness product policy.

According to what has been described in your submission, we believe that your product is not a "device" as that term is defined in Section 201(h) of the Act. Therefore, you are not required to comply with the requirements of the Act. Please note, if you later revise your indications to add medical claims, you may need a premarket notification [510(k)] submission.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1- 800-638-2041 or 301-796-7100).

If you have any questions regarding this letter, please contact CAPT Elizabeth Claverie, M.S., Assistant Director, THT4B2, at 301-796-6298.

Sincerely,

David Krause

Office of Surgical and Infection Control Devices