February 15, 2019

Safe Haven Baby Boxes, Inc.
Monica Kelsey
Official Correspondent
P.O. Box 185
Woodburn, Indiana 46797

Re: C180100
Product Name: Safe Haven Baby Box
Dated: October 31, 2018
Received: December 19, 2018

Dear Monica Kelsey:

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 Safe Haven Baby Box. As 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 Alan Stevens, Chief, General Hospital Devices Branch, at 301-796-6294.

Sincerely,

Angela C. Krueger -S

Angela Krueger
Deputy Dir., Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health