10/13/2022

Inamed Development Co.
Ellen Duke
Director, Regulatory Affairs and Product Introduction
1035B Cindy Lane
Carpinteria, California 93013

Re: K904265
Trade/Device Name: Inamed Ruiz-Cohen Intraoperative Tissue Expander
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: Class I
Product Code: FZW

Dear Ellen Duke:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 6, 1991. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code FZW.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Deborah Fellhauer, OHT4: Office of Surgical and Infection Control Devices, 301-796-9570, Deborah.Fellhauer@fda.hhs.gov.

Sincerely,

Deborah A. Fellhauer -S
Deborah A. Fellhauer -S
2022.10.13 13:16:02
-04'00'

Deborah A. Fellhauer RN, BSN
Assistant 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