**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 22, 2016

Inotech Kunststofftechnik GmbH
Zahed Sedighiani
Quality and Regulatory Affairs Manager
Boschstr. 3
Nabburg D-92705, Germany

Re: K160163
Trade/Device Name: Cardio First Angel
Regulation Number: 21 CFR 870.5210
Regulation Name: Cardiopulmonary Resuscitation (CPR) Aid
Regulatory Class: Class II Exempt
Product Code: PMJ
Dated: June 27, 2016
Received: June 30, 2016

Dear Zahed Sedighiani:

We have reviewed your premarket notification submission and believe this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act).

Based on the device description included in your submission, it appears that your CPR aid provides feedback but does not contain software (e.g., is mechanical or electro-mechanical). The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 870.5210. When listing your device with the Food and Drug Administration (FDA), please use the product code shown above. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). You must also comply with the special controls in 21 CFR 870.5210(b)(2).

We recommend that you review the limitations to the exemption in 21 CFR Section 870.9. Please note that if you modify your device in the future such that you introduce a new indication for use or a different fundamental scientific technology to the above-referenced classification regulation, your device may exceed the limitations to the exemption and may consequently require 510(k) clearance prior to marketing this device in the United States.

Please be advised that the statements in this letter do not mean that the FDA has made a determination that your product complies with other requirements of the Act and FDA regulations or any Federal statutes and regulations administered by other Federal agencies. It is your responsibility to ensure compliance with all applicable requirements under the Act and FDA regulations.

Please be advised that Title 21 Code of Federal Regulations, Part 807, Subparts A-D, requires all establishments, whether foreign or domestic, that are engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into or distribution in the U.S. to register and list with the FDA. If you have any questions regarding the registration and listing requirements, please call 301-796-7400.

If you have any questions regarding this letter, please contact Eric Richardson, at 240-402-3758 or please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Fernando Aguel -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health