



December 5, 2019

Zoll Medical Corporation
Elizabeth McMeniman
Director, Regulatory Affairs
269 Mill Rd
Chelmsford, Massachusetts 01824

Re: P160022

Trade/Device Name: X Series®, R Series®, Propaq® MD, AED Pro®, AED 3™ BLS Professional Defibrillators, Pro-Padz Radiotransparent Electrode, SurePower™ Battery Pack, SurePower II™ Battery Pack, AED Pro® Non-Rechargeable Lithium Battery Pack, AED 3™ Battery Pack, SurePower™ Charger, and SurePower™ Single Bay Charger

Dear Elizabeth McMeniman:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its review of your premarket approval application (PMA) and issued an approval order on December 27, 2017. We inadvertently made an error in omitting the Propaq® MD Defibrillator from the original approval order.

We hope that this omission has not inconvenienced you. If you have any questions about this corrective action, please contact Jennifer Shih at 301-796-5813 or Jennifer.Shih@fda.hhs.gov.

Sincerely,

Jessica E. Paulsen -S
for
Bram Zuckerman, M.D.
Director
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health