

Premarket Approval (PMA)

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Device	AED 3 Defibrillator With Uni-Padz
Generic Name	Automated External Defibrillators (Non-Wearable)
Regulation Number	870.5310
Applicant	ZOLL MEDICAL CORPORATION 289 & 271 Mill Road Chelmsford, MA 01824
PMA Number	P160015
Supplement Number	S004
Date Received	03/27/2020
Decision Date	06/05/2020
Product Code	MKJ
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track No User Fee
Supplement Reason	Postapproval Study Protocol
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval of the protocol for the post-approval study (PAS) protocol.

Page Last Updated: 11/01/2021

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