Premarket Approval (PMA)

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the original PMA[23] record for more information.

Device	PARADIGM REAL TIME SYSTEM
Generic Name	Sensor, glucose, invasive
Applicant	MEDTRONIC MINIMED 18000 DEVONSHIRE ST NORTHRIDGE, CA 91325
PMA Number	P980022
Supplement Number	S013
Date Received	10/04/2005
Decision Date	04/07/2006
Product Codes	OYC[24] MDS[25]
Advisory Committee	Clinical Chemistry
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/Components/Specifications/Material
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

APPROVAL FOR MODIFICATIONS TO THE MMT 515/715 EXTERNAL INSULIN PUMP AND TO THE GUARDIAN RT SENSOR TO ENABLE THE PUMP TO ACCEPT DATA FROM THE SENSOR, AND TO ENABLE THE SENSOR TO COMMUNICATE DIRECTLY TO THE PUMP. THE DEVICE WILL BE MANUFACTURED AT MEDTRONIC MINIMED, NORTHRIDGE, CALIFORNIA.

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Page Last Updated: 07/17/2023

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