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Premarket Approval (PMA)



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