FDA/EMA Medical Device Product Registration Tracker

Medtronic MiniMed 780G System

Product Registration Summary

United States (FDA)

Field	Value
Regulatory Agency	FDA (Food and Drug Administration)
Product Name	MiniMed 780G System
Manufacturer	Medtronic MiniMed, Inc.
Device Classification	Class III
Regulatory Pathway	PMA (Premarket Approval)
Registration Number	P160017/S076
Approval Date	April 28, 2023
Indication for Use	Automated insulin delivery system for the management of Type 1 diabetes mellitus in persons two years of age and older
Patient Population	Ages 2 and older
Approval Status	Active
Notes	Supplement to original PMA P160017. Hybrid closed-loop system with SmartGuard technology for automated basal insulin adjustment.

European Union (EMA)

Field	Value
Regulatory Agency	EMA (European Medicines Agency) via Notified Body
Product Name	MiniMed 780G System
Manufacturer	Medtronic MiniMed, Inc.
Device Classification	Class IIb
Regulatory Pathway	CE Mark (MDR 2017/745)
Registration Number	CE 0123
Approval Date	November 2020
Indication for Use	Automated insulin delivery system for the management of Type 1 diabetes mellitus in persons seven years of age and older
Patient Population	Ages 7 and older
Approval Status	Active
Notes	CE marked under EU Medical Device Regulation (MDR) 2017/745. Notified Body: TÜV SÜD Product Service GmbH (CE 0123).

Key Regulatory Differences: US vs. EU

Aspect	US (FDA)	EU (EMA)
Classification	Class III	Class IIb

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Pathway	PMA	CE Mark (MDR)
Review Body	FDA (centralized)	Notified Body (decentralized)
Patient Age	2 years and older	7 years and older
Approval Date	April 2023	November 2020

For portfolio demonstration purposes