Review Summary

July 23, 2026

Pharmaceuticals and Medical Devices Agency

The following is the summary of the review of the following medical device submitted for marketing approval conducted by the Pharmaceuticals and Medical Devices Agency (PMDA).

Classification	:	Instrument & Apparatus 74, Drug infusion apparatus
Term name	:	Portable insulin infusion pump
Brand name	:	Medtronic Minimed 700 Series
Applicant	:	Medtronic Japan Co., Ltd.
Date of application	:	December 16, 2025
Date of approval	:	May 20, 2026
Application classification	:	☐New medical device ☒Improved medical device (with clinical data) ☐Improved medical device (without clinical data)
New approval / Partial change	:	☐New Approval ☒Partial Change
Review category	:	☐Brain and Circulatory Medicine, Respiratory Medicine, Neurology, and Psychiatry ☐Cardiopulmonary Circulation ☐Dentistry and Oral Medicine ☐Gastroenterology, Genitourinary, and Reproductive Medicine ☐Ophthalmology and Otorhinolaryngology ☐Orthopedic and Plastic Surgery ☒Robotics, IoT, and other devices (not classified as other categories) ☐Program D1 ☐Program D2
Items warranting special mention	:	☐Designated as medical devices with high medical need ☐Designated as specific-usage medical device ☐Application in accordance with conditional early approval system for medical devices (Type 1) ☐Application in accordance with conditional early approval system for

medical devices (Type 2: “Physical operation of items’ extrapolative and inclusive approval” (Phoenix))

☐Application in accordance with the notification on pre- and post-market rebalancing (☐1st step ☐2nd step)

☐Application in accordance with “Improvement design within approval for timely evaluation and notice” (IDATEN)

☐Designated as orphan medical device

☐Application in accordance with the 0929 notification

☐Other ( )

Expert Discussion : ☐Yes ☒No

1. Submitted data

(1) Background of the development

This product is an infusion pump for portable insulin used for monitoring interstitial fluid glucose and for continuous subcutaneous administration of basal insulin at a selectable rate and for administration of a selectable amount of insulin bolus. The purpose of this application is to change the applicability of the Model 780G automode function from patients with type 1 diabetes who are 7 years of age or older to patients with diabetes mellitus (type 1 diabetes and other diabetes mellitus who are 2 years of age or older and type 2 diabetes who are 18 years of age or older) who are severely impaired with insulin secretion.

(2) Non-clinical Data

In this application, no changes were made to the product itself. Therefore, the submission of evaluation data on nonclinical data was omitted.

(3) Clinical Data

The applicant presented the results of the CIP341 and CIP342 studies conducted in the United States and Europe. The summary of CIP341 and CIP342 studies is as follows (reference to the clinical data section of the package insert and table numbers, etc., are provided as necessary).

The following clinical studies were conducted to confirm the efficacy and safety of Auto Mode (Auto Correction bolus).

<<Testing based on sensor glucose values in Guardian 4 system >>

1. CIP342 study (study phase)

A 12-week clinical trial (randomised crossover study) was conducted in patients 2 to 6 years of age with

type 1 diabetes using a Model 780 G pump.

Table 1 Glucose Control During Study Period

	Control group		Treatment group	
Number of patients	98 patients		98 patients	
Parameter	Start of the study	At the end of the study	Start of the study	At the end of the study
Sensor glucose, mean ± SD mg/dL	169.6±25.7 (97 cases)	169.1±23.1 (97 cases)	169.6±25.7 (97 cases)	150.2±10.7 (97 cases)
HbA1c mean ± SD %	7.5±1.0	7.6±0.9 (Number of cases: 96)	7.5±1.0	7.0±0.5 (97 cases)
Percentage of time that the glucose value was within the range during the study period				
SG≦54mg/dL	0.7±0.8		0.9±0.8	
SG≦70mg/dL	3.5±2.1		4.6±2.2	
70<SG≦180mg/dL	58.3±12.5		68.3±6.9	
SG>180mg/dL	38.1±13.0		27.1±6.4	
SG>250mg/dL	13.1±9.5		7.7±4.6	
SG>350mg/dL	1.9±3.1		1.0±1.4	

No device-related SAEs were reported.

The results demonstrated improved safety and glucose control in auto mode (auto-corrected bolus).

2. CIP341 study (Phase 1)

A 3-month clinical study (single-arm study) was conducted using a Model 780G pump for type 2 diabetes mellitus aged 18 years or older.

Table 2 Glucose Control During Study Period

Number of patients	89 patients	
Parameter	Start of the study	At the end of the study
Sensor glucose, mean ± SD mg/dL	157.1±22.4 (Number of patients: 95)	147.5±15.2 (Number of cases: 91)
HbA1c mean ± SD %	7.9±1.0 (Number of patients: 95)	7.2±0.7 (Number of patients: 88)
Percentage of time that the glucose value was within the range during the study period Mean ± SD (95% CI), %		

SG<54mg/dL	0.0±0.1
SG<70mg/dL	0.3±0.4
70≦SG≦180mg/dL	79.8±11.4
SG>180mg/dL	19.9±11.5
SG>250mg/dL	2.6±3.8
SG>350mg/dL	0.1±0.4

No device-related SAEs were reported.

The results demonstrated improved safety and glucose control in auto mode (auto-corrected bolus).

<<Test based on value of sensor glucose by Simplera Sync >>

1. CIP342 study (Continuation phase)

   A 12-week clinical trial (randomised crossover study) was conducted in patients 2 to 6 years of age with type 1 diabetes using a Model 780 G pump.

Table 3 Blood glucose control during study period

	Guardian 4 sensor group		Simplera Sync group	
Number of patients	46 patients		46 patients	
Parameter	Start of the study	At the end of the study	Start of the study	At the end of the study
Sensor glucose, mean ± SD mg/dL	150.1±11.8 (Number of cases: 91)	151.3±13.4	150.1±11.8 (Number of cases: 91)	152.5±12.1 (44 cases)
HbA1c mean ± SD %	7.2±0.6 (Number of cases: 83)	7.2±0.6 (Number of patients: 42)	7.2±0.6 (Number of cases: 83)	7.3±0.5 (Sample size: 38)
Percentage of time that the glucose value was within the range during the study period				
SG≦54mg/dL	0.8±0.8		0.4±0.3	
SG≦70mg/dL	4.1±2.3		2.9±1.4	
70<SG≦180mg/dL	68.9±8.6		69.7±7.7	
SG>180mg/dL	27.1±8.0		27.5±7.7	
SG>250mg/dL	7.8±5.9		7.6±4.7	
SG>350mg/dL	1.1±1.8		0.8±1.4	

No device-related SAEs were reported.

The results demonstrate that the safety of auto mode (auto correction bolus) using a Simplera Sync and the control of glucose values are non-inferior to auto mode using a guardian 4 sensor.

2. CIP341 study (Phase 2 Naïve subjects only)

A 3-month clinical study (single-arm study) was conducted using a Model 780G pump for type 2 diabetes mellitus aged 18 years or older.

Table 4 Blood glucose control during study period

Number of patients	228 patients	
Parameter	Start of the study	At the end of the study
Sensor glucose, mean ± SD mg/dL	152.9±21.2 (Sample size: 236)	140.7±13.3 (Number of cases: 232)
HbA1c mean ± SD %	7.7±0.9 (Sample size: 236)	6.9±0.7 (Number of cases: 229)
Percentage of time that the glucose value was within the range during the study period Mean ± SD (95% CI), %		
SG<54mg/dL	0.0±0.1	
SG<70mg/dL	0.3±0.4	
70≦SG≦180mg/dL	84.9±9.7	
SG>180mg/dL	14.8±9.7	
SG>250mg/dL	1.7±2.5	
SG>350mg/dL	0.1±0.2	

No device-related SAEs were reported.

The results demonstrated improved safety and glucose control in auto mode (auto-corrected bolus).

2. Review Results

PMDA has reviewed the submitted materials and concluded that the application is approvable.

<Intended Use>

The purpose of this system is to deliver basal insulin continuously at a selectable rate and to administer a selectable amount of insulin bolus.

Model 770G

The system's automode automatically adjusts basal insulin for type 1 diabetes based on values obtained from continuous glucose monitoring (CGM).

Model 780G

The automode system automatically adjusts the basal insulin and the corrected bolus for diabetes mellitus with severely impaired insulin secretion based on the values obtained from continuous glucose monitoring (CGM).