

K241335 Eversense 365 Continuous Glucose Monitoring (CGM) System

Sep 16, 2024
126 days to decisionK241335 · Product code: **SBA** · Chemistry
Source: <https://www.510kdatabase.net/k241335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System With Sensor Containing Dexamethasone Acetate (SBA)
Date received	May 13, 2024
Decision date	Sep 16, 2024
Days to decision	126 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Senseonics, Incorporated
Location	Geramantown, MD, US
Contact	Mukul Jain
510(k) history	2 submissions · 1 cleared · 2024-2024

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