

K222280 Bigfoot Unity® Diabetes Management SystemMar 1, 2023
215 days to decisionK222280 · Product code: **QLG** · Chemistry
Source: <https://www.510kdatabase.net/k222280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated, Not For Use With Automated Insulin Delivery Systems (QLG)
Date received	Jul 29, 2022
Decision date	Mar 1, 2023
Days to decision	215 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bigfoot Biomedical, Inc.
Location	Milpitas, CA, US
Contact	Kate Lee
510(k) history	2 submissions · 2 cleared · 2021-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222280/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026