

K222327 Bloomlife MFM-ProFeb 13, 2023
195 days to decisionK222327 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k222327/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Aug 2, 2022
Decision date	Feb 13, 2023
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bloom Technologies NV
Location	Genk, BE
Contact	Roberto Cunha
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Bloomlife, Inc.
Contact	Roberto Cunha

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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