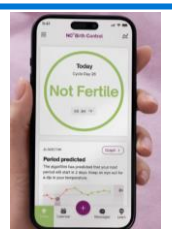
Software as a Medical Device (SaMD) – *When and how is software regulated as a "medical device"? When is it a med device vs. a wellness product?*

SaMD definition: "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."[1]

- Medical purposes: diagnosis, prevention, monitoring, treatment or alleviation of disease
- **Regulation:** medical device (FDA Class I/II/III); FDA guidance available on risk categorization & documentation requirements[2, 3]

Apple Watch ECG app makes claims on diagnosing A-fib[4, 5]



Natural Cycles app makes claims on contraception effectiveness (93%)[6, 7]

Software is not a med device, but a "low-risk general wellness product" if: (1) only for general wellness use, AND (2) low safety risk.[8]

- Encourages a general state of health or a healthy lifestyle as it relates to reducing the risk or impact of certain chronic diseases
- **Regulation:** exempt from FDA medical device regulations

BetterSleep app tracks and records sleep, may help living with anxiety[9]

Impulse Brain app offers games for memory & concentration[10]

Other software classifications[11]**:**

- Software that is integral to a medical device (software *in* a medical device)
  - Example: software within a ventilator, infusion pump, pacemaker
- Software used in the manufacture or maintenance of a medical device
  - Example: software that monitors x-ray tube performance

Software *in* a medical device

Software *monitoring* a medical device

Case Study: Owlet Baby Monitor

FDA issued a warning letter to Owlet stating its *Smart Sock* was subject to FDA medical device regulation because it was "intended to identify (diagnose) desaturation & bradycardia." Owlet then discontinued its *Smart Sock* product in the US & launched *Dream Sock*, which has no diagnostic claims.[12, 13]

Remember: *What is claimed about a software & how it's marketed impacts its classification!*

Sources: 1). IMDRF Software as a Medical Device (SaMD) Working Group. (2014). "Software as a Medical Device": Possible Framework for Rise Categorization and Corresponding Considerations. International Medical Device Regulator Forum (IMDRF). International Medical Device Regulators Forum., 2). FDA. (2023). Content of Premarket Submissions for Device Software Functions. https://www.fda.gov/media/153781/download., 3). FDA. (2020, July 2). Classify Your Medical Device. U.S. Food and Drug Administration. https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device., 4). FDA. (2018). DE NOVO CLASSIFICATION REQUEST FOR ECG APP. Retriebed March 29, 2023 from https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180044.pdf., 5). Apple. (2011). Healthcare - Apple Watch. Apple. https://www.apple.com/healthcare/apple-watch/., 6). FDA. (2017). DE NOVO CLASSIFICATION REQUEST FOR NATURAL CYCLES. Retrieved March 29, 2024, from https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170052.pdf., 7). How Effective is Natural Cycles ? | Compare Birth Control. (2021, February 3). Natural Cycles. https://www.naturalcycles.com/how-effective-is-natural-cycles., 8). General Wellness: Policy for Low Risk Devices Guidance for Industry and Food and Drug Administration Staff Food and Drug Administration Center for Devices and Radiological Health. (2016). https://www.fda.gov/media/90652/download., 9). BetterSleep | Sleep better. Feel Better. https://www.bettersleep.com/., 10). Impulse - Brain Training Games. (2024, March 29). App Store. https://apps.apple.com/ca/app/impulse-brain-training-games/id1451295827., 11). Health, C. for D. and R. (2022). What are examples of Software as a Medical Device? FDA. https://www.fda.gov/medical-devices/software-medical-device-samd/what-are-examples-software-medical-device., 12). Health, C. for D. and R. (2021, October 26). Owlet Baby Care, Inc. - 616354 - 10/05/2021. FDA. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/owlet-baby-care-inc-616354-10052021., 13). FDA Response. Owlet Baby Care US. https://owletcare.com/pages/fda-response.