Nightscout FDA presubmission

Release 0.0.1

Nightscout contributors

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ONE

COVER LETTER

1.1 a. Cover Letter

This presubmission is to discuss open source projects and FDA oversight. Specifically, this is to discuss the Nightscout project.

1.1.1 Pre-Sub for Nightscout

To whom it may concern, Stayce Beck, et al.

For CDRH submissions, the addressee may be the appropriate branch or branch chief if the applicant knows where the subject device or similar devices are reviewed. For CBER submissions, the addressee may be the appropriate Office Director or Regulatory Project Manager where the subject device or similar devices are reviewed. The cover letter should

> http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm279288.htm 24 CDRH Premarket Review Submission Cover Sheet available at
>
> http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf Contains Nonbinding Recommendations

contain complete contact information (i.e., the company name, address, contact person, phone number, fax number, and email address). In addition to describing the reason for the submission in the reference line, the cover letter should also clearly identify the name of the device and include the signature of the contact person, or other responsible party.

CHAPTER

TWO

NIGHTSCOUT

Nightscout is a suite of open source projects. A smartphone provides ubiquitous network connectivity to Dexcom's wireless receiver. After a polling period the last reading from the Dexcom reciever is transmitted to a database in the cloud. A website renders near-real-time views of the records stored.

2.1 Device Description

2.1.1 Nightscout project

The Nightscout project is actually a suite of several independent projects:

- dexcom-uploder - Android app to poll dexcom, upload to cloud
- cgm-remote-monitor - A node.js web application that displays values stored by the Dexcom.
- cgm-pebble - A pebble watchface that reads and displays values from cgm-remote-monitor.

cgm-remote-monitor

This is a web app which simulates the display of a Dexcom receiver. In addition to showing the last known glucose level, it displays when the reading was taken, and offers a way to pan several hours retrospectively.

dexcom-uploader

dexcom-uploader is an Android application implemented in java. The application starts when a Dexcom receiver is detected using the operating system's usb management system. The application reads data from the serial port made available by Dexcom's usb connection, and uploads the latest record to a specified data backend. The backend may either be a RESTful API or a mongo db, and is configured using a preferences panel inthe application.

cgm-pebble

cgm-pebble is a C and javascript watchface developed using PebbleSDK. The javascript code runs on a Smartphone maintaining bluetooth connectivity to the Pebble watch. The javascript code retrieves information from *cgm-remote-monitor* and sends the last reading to over bluetooth to the pebble watch. The C code runs on the watch, receiving messages over bluetooth from a smarthphone, and rendering the date, time, value, and trend reported by *dexcom-uploader*.

2.1.2 Development

Development takes place using github, from the nightscout organization page: https://github.com/nightscout/. Modifications, upgrades, development, and issue tracking happen using the resources connected to assets shared by a community of people.

2.1.3 c. Device Description

Please provide sufficient information regarding the device description, 25 which may include:

- pictures of the device (where applicable);
- engineering drawings (where applicable);
- physical, chemical and/or biological processes/principles used by the device to generate device output, if applicable;
- physical and biological characteristics of the device output, if applicable;
- samples to demonstrate the use of the device (where feasible and appropriate);
- explanation of the user interface and/or how the device interacts with other devices or with the user (medical professional and/or patient);
- explanation of the materials used in the device;
- a brief explanation of how the device is manufactured (where necessary);
- discussion of the mechanism of action and how the device and/or, if applicable, device output is used;
- for an IVD, detailed technical description of your device including instruments, reagents, components, software, principles of operation, and accessories (if there are changes to a previously cleared or approved device, then you should describe these changes);
- discussion of the scientific basis for development of the device or an explanation of expected clinical utility; and
- for a device to be submitted in a 510(k), any anticipated predicate and a descriptive comparison of the device to the predicate device.

In addition to pictures and a written description, other information about the clinical use of the device, such as a surgical technique guide or video of how the device is used in the clinical setting, may be helpful.26

CHAPTER

THREE

PROPOSED USE

3.1 Nightscout

Nightscout is intended to be used as part of a data management system. The system provides for a "glanceable" secondary display of the information originating from the Dexcom CGM. A website allows the display to be presented on any device which can display websites to duplicate the display of the Dexcom.

3.1.1 Single pane of glass

The website url is typically shared with caregivers and interested parties. This allows multiple people to monitor a Dexcom user's glucose levels from concurrently from any internet connection.

3.1.2 Glanceability

Displays are duplicated in multiple redundant locations. This alleviates people from needing to physically locate and attend to the receiver. The lowered burden enables people to be more persistently aware, and therefore respond to scenarios with treatment with greater ease.

For example, in scenarios where no therapeutic action is required, but the glucose levels must be considered, the glanceable display eliminates the 30 second interuption to an existing workflow.

d. Proposed Intended Use/Indications for Use

Please provide sufficient information regarding the proposed intended use/indications for use,

which may include:

- identification of the disease or condition the device is indicated to prevent, mitigate, screen, monitor, treat, or diagnose;
- identification of the target population;
- part of the body or type of tissue to which applied or with which the device is interacting;
- frequency of use;
- physiological use; and
- statement of whether the device is intended for prescription and/or over-the-counter use.

For an IVD device, this information should include a detailed draft of the intended use of the device including the intended use population, the analyte/condition to detect, and the assay methodology (see Section F of Appendix 1 for more detailed information).

CHAPTER

FOUR

PREVIOUS WORK

4.1 e. Previous Discussions or Submissions

Please summarize any previous discussions with/submissions to (including submission numbers) the agency on this or a similar device (e.g., previous discussions on a prior device design), including submission numbers as appropriate.

CHAPTER

FIVE

OVERVIEW OF PRODUCT DEVELOPMENT

5.1 Development of Nightscout

A loose coallition of individuals all corroborate using tools that are in common use across the internet. The Nightscout project came about after several individuals disatisfied with how their diabetes data was being treated and presented to them needed a better way to manage and view the data.

Git is used to track proposed changes to the source code.

5.1.1 Instructions

Please provide an overview of the product development, including an outline of nonclinical and clinical testing either planned or already completed. However, please note that our review of a Pre-Sub will not include a review of bench or clinical data that you have already collected.

If you intend to include complete copies of literature articles as part of this section, please try to include only those that are relevant to the questions you are asking. Additional articles can be provided in any subsequent marketing application or IDE.

CHAPTER

SIX

SPECIFIC QUESTIONS

6.1 Intended use

- Is this a secondary or passive or active display?
- What does distributing many? Does posting code on a website (eg github) that must be deployed and configured count as free speech or regulated activity?

6.2 g. Specific Questions

The Pre-Sub should include specific questions regarding review issues relevant to a planned IDE, or marketing application (e.g., questions regarding pre-clinical and clinical testing protocols or data requirements) as our advice will be guided by your questions and may not identify all submission requirements. Appendix 1 of this guidance contains sections specific to IDE, 510(k), PMA, and HDE that list examples of questions appropriate to each submission and application type.

CHAPTER

SEVEN

FEEDBACK

7.1 h. Method for Feedback

You should specify how you prefer FDA to provide the feedback you are seeking. You may request our feedback through an in-person meeting, a teleconference, facsimile, or by email. Please note that FDA will ultimately decide the means of communicating the feedback, but will consider the desired method requested in the Pre-Sub. If FDA has already agreed to a meeting, it is the sponsor's decision regarding whether this previously scheduled meeting should occur even if FDA has provided a written response to the sponsor's questions. If we provide feedback through a meeting or teleconference, the final meeting minutes will be considered FDA's formal written feedback (see Section IV.D. below).

If you are requesting a meeting or teleconference as the method for feedback, your submission should include:

- the meeting format you are requesting (i.e., in-person or by teleconference);
- three (3) or more preferred dates and times when you are available to meet using the guidelines in Table 1 above for scheduling;
- the planned attendees, including each attendee's position, or title, and affiliation. If you have not yet identified all of your attendees, you should indicate the type of subject matter experts you plan to invite so that we can ensure appropriate FDA experts are in attendance. Please note foreign visitors meeting in an FDA facility require advanced security clearance. See Section IV. B. "Security Screening" below for additional information on how to request security clearance for Foreign Nationals; and
- a list of any audiovisual equipment you will need, such as conference phone or LCD projector.

You should propose the duration of the meeting you are requesting. In our experience, one (1) hour is adequate for most meetings. If you believe that more than one (1) hour is needed, please provide a rationale for the duration you propose. You should also refer to the rationale and confirm the duration requested when the division contact person schedules your meeting.

We recommend that your agenda allocate the last ten (10) minutes of the meeting for summarizing the discussions and any next steps or action items.

CHAPTER

EIGHT

ABOUT

In open source fashion, this document's raw source, pdf version and an html rendering is available online. The purpose is to create a framework for having a discussion with the FDA.

CHAPTER

NINE

INDICES AND TABLES

- *genindex*
- *modindex*
- *search*