decoding-carelink FDA presubmission Documentation

Release 0.0.1

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Contents:

COVER LETTER

1.1 a. Cover Letter

Please include a cover letter that clearly states the reason for the submission in the reference line (e.g., Pre-Sub for a 510(k), Pre-Sub for an IDE, Pre-Sub for an IND or BLA) and, for CDRH submissions, please clearly indicate that the submission is a Pre-Sub on the CDRH Premarket Review Submission Cover Sheet. 24 Use of the CDRH Premarket Review Submission Cover Sheet for submissions made to CBER is highly recommended.

1.1.1 Pre-Sub for

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/ucm27

9288.htm 24 CDRH Premarket Review Submission Cover Sheet available at

http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080872.pdf ontains Non-binding 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.

TWO

COMLINK2 DRIVER

The device, `decocare`, is a comlink2 driver, a software library, which implements methods and functions to facilitate communication between Paradigm-compatible RF devices and data management application software using the Carelink USB stick from Medtronic (MMT-7305NA).

2.1 Device Description

2.1.1 decocare - the library

Decocare is the name of a python package, a re-usable suite of python source modules, which implements functions and methods to encode and decode messages compatible with the `ComLink2` protocol used by the MMT-7305NA Carelink USB stick.

Usage

The library allows authors of python source code to write methods needed to implement data management software. In order to use the library, authors need to download the python package, configure their local system to use the module, write new python source code implementing the desired remote management features, then execute their newly written source.

The library contains a listing of different messages, commercially supported by Medtronic, allowing data management software to remotely communicate with compatible devices. The messages, and the list of messages made available by the library is intended to correspond directly to the list of messages currently in use by Medtronic products.

Dissemination

The source code is distributed using `git`, a version control system, ensuring that changes or versions of the source code are kept in sync.

A user must know how to configure and use python modules and git in order to install the software on a local PC.

The git repo, is hosted online https://github.com/bewest/decoding-carelink available as an educational resource for discussing potential applications of remote management software.

Installing

In order to run the software, the source must be retrieved, deployed and configured to run on a PC. Currently the user must know how to perform these steps, the easiest way is on the commandline:

git clone https://github.com/bewest/decoding-carelink.git

cd decoding-carelink
sudo python setup.py install

2.1.2 mm-* tools, investigational tools

Another set of devices are tools showing example usage of the library, and tools to investigate how the library and the serial protocol are used to communicate with the remote equipment work.

These tools facilitate use of the decocare library to exchange messages with the usb stick, to audit the operation of the usb stick, as well as to exchange and record messages with remote RF equipment for debugging and analysis.

After configuring and installing the tool, these tools allow initializing RF communications with compatible devices, exchanging a series of predefined or customized commands, and saving the results for later perusal.

These tools support communicating with remote Paradigm-compatible equipment using commands supported by Medtronic in other commercial products, in exactly the same way as those products, from the command line, shell environment. The following options allow users to control how remote equipment is uniquey addressed or distinguished from other compatible devices, and how communication begins.

--init Send remote signal to initialize RF communication.

--serial Only communicates with the remote equipment responding to this serial number. This matches the number, I.E. on the back of Medtronic insulin pumps.

`mm-send-comm.py` allows sending or customizing commands Medtronic intends to support using their own software and devices.

`mm-latest.py` Example showing construction of data management software using the Carelink usb and protocol. Uses same commands as Carelink in a demonstration to query the given minutes of history and pump activity.

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

PROPOSED USE

3.1 Intended Use of MMT-7305NA

Decocare is an open source driver for a commercially available device, the MMT-7305NA. The user's guide: http://www.medtronicdiabetes.com/sites/default/files/library/support/carelink_usb_user_guide.pdf indicates intended use is:

> Indications for use The Medtronic CareLink™ USB is indicated for use by patients at home and clinicians in a medical office setting to facilitate communication between Medtronic diabetes therapy management devices that use Paradigm-compatible RF telemetry (MWT1)* and a personal computer that uses data management application software.

3.2 Intended Use of decocare

Provides methods and utilities to facilitate communication between Paradigm-compatible devices and data management application software.

3.2.1 Observing device behavior

Decocare helps observe the behavior of MMT-7305NA and compatible medical devices in greater detail. The tools expose diagnostic information regarding successful transmission of messages to the device, as well as allows users to precisely audit and log device behavior.

A user may use the `mm-send-comm.py` tool to request and save a page of data, as it existed on the pump.

3.2.2 Creating data management software

Decocare allows python authors to create data management tools. Decocare transfers messages from a data management application to remote devices and back. An application developer can use this facility to create a program which uses the `ReadHistoryData` command, decodes the information, and presents it to the user or saves it for later use.

3.3 Frequency of use

We are unsure what Medtronic's recommendation is regarding how frequently remote equipment may communicate with application software.

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).

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.

OVERVIEW OF PRODUCT DEVELOPMENT

5.1 Development of decocare

The library was developed by via careful analysis of messages passed between Medtronic's Carelink software, blood glucose meters equipped with the feature known as `meter-link`, Medtronic's pump remote control, Carelink software, and the carelink usb stick.

Messages from the Carelink data management application software were analyzed for structure and semantics. Python code was then written to recreate the messages needed to successfully transfer data from remote equipment to a local application. The full logs and output from each experiment were captured in git for additional debugging and perusal.

The software includes a suite of tests. Many of the tests will prevent the software from running in an abnormal condition is found in the tests. The Carelink USB stick offers a facility for counting how many messages have been sent and recieved in error, corrupted, or successfully. All experiments capture the status of these counters at the beginning and end of each use to provide diagnostic information on the operation of the usb stick. This information can be helpful in determining if the protocol is exchanging messages as Medtronic intended.

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.

SPECIFIC QUESTIONS

6.1 Intended use

- What is intended use of carelink stick MMT-7305NA?

- What are intended use of commands/messages sent to MMT-7305NA from application

- Does Medtronic/FDA know of any bugs triggered by these commands sent to/from MMT-7305NA that may cause unexpected behavior, or behavior other than originally intended?

6.1.1 Use of MMT-7305NA

The instruction manual indicates that the usb stick is intended for use by patient or doctor to exchange messages between a data management application and compatible medical devices. The instruction manual does not seem to include any instructions demonstrating use of the usb stick. It also does not indicate semantics for messages transferred to remote equipment.

The MMT-7305NA was designed to exchange all messages that remote equipment supports, but no instructions on usage are available from its sponsor.

The messages facilitate creating a record of treatment. Should patients be able to get a copy of their records as the pump produces them?

- What if the vendor software does not work?

- How does use of MMT-7305NA affect remote equipment, ie battery life of pump, total number of capitance charge cycles, etc...

    - Is this part of intended use of MMT-7305NA?

Commands

The MMT-7305NA is capable of exchanging many different types of commands, each with a different intended purpose. Are each of these certified/pre-subed separately? Different equipment and models respond differently to different commands. Are there any indications how these commands are intended to be used with these devices?

- What if decocare only sends commands supported by each device?

    - Does it stay within the intended use of vendor?

- What is intended use case for the remote control?

    - If the remote exchanges a message to bolus, a new tool, eg, `mm-send-bolus-example.py` both send the exact same message, is the tool covered by the remote's use case?

- Are there commands which trigger otherwise unexpected behavior?

  - Are there firmware bugs known to exist in different models, eg 1.16 vs 1.17, suspend bug?

  - If some commands are less stable with regard to behavior in the firmware, should the vendor share this information with users of the device? Should it be in the instruction manual?

Should MWT1's commands be documented so that users know what each command is intended to do?

Fault / responsibility

If something goes wrong who is at fault? Depends on what goes wrong whether or not device was used according to intended use or not. What is the intended use of the MMT-7305NA, how will users use it, how do users get support?

Future software devices

Authors using decocare could create additional tools:

- logging

  - log all history

  - query for recent history

- audit

  - create log of device behavior

  - injury/adverse event reporting tool might automatically compile report of all injurious events in therapy history and submit to FDA

- bolus wizard

  - bolus wizard on the web/browser

  - bolus wizard on mobile

  - bolus wizard from laptop

  - bolus wizard from data management software

- artificial pancreas

  - auto suspend

  - auto temp basal

  - auto bolus

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.

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.

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.

INDICES AND TABLES

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