TO: Q240410/S001
Attn: Zach McKinney, PhD, Lead Reviewer, CDRH/OPEQ/OHT5
FROM: Megan Moynahan MS, Case Western Reserve University
DATE: May 14, 2024
RE: Meeting minutes from presubmission meeting dated April 30, 2024

CWRU Team
Megan Moynahan, MS
Kevin Kilgore, PhD
Cindy Chestek, PhD
Chris Rexroth

NIH/NINDS SPARC
Brooks Gross, PhD, Program Officer

FDA Team

Pre-Submission Teleconference: List of FDA Participants

Q240410 (COSMIIC Networked Neuroprosthesis)

April 30, 2024

Name	FDA Center/Office	Review Role/Function
Zach McKinney, PhD	CDRH/OPEQ/OHT5	Lead Reviewer
Stacy Monza	CDRH/OPEQ/ORP	Master File Program Expert Reviewer
Shelby Skoog, PhD	CDRH/OPEQ/OHT5	Biocompatibility Expert Reviewer
Tushar Bansal, PhD	CDRH/OPEQ/OHT5	Team Lead – Acute Injury Devices
Julia Slocomb, PhD	CDRH/OPEQ/OHT5	Senior Lead Reviewer (observing)
David McMullen, MD	CDRH/OPEQ/OHT5	Office Director, OHT5
Kai Kadoich	CDRH/OCD	Total Product Lifecyle Advisory Program (TAP) Program Advisor

Legend: FDA Components
- CDRH: Center for Devices and Radiological Health
- OPEQ: Office of Product Evaluation and Quality
- OHT5: Office of Health Technology 5 – Neurology & Physical Medicine Devices
- ORP: Office of Regulatory Programs
- OCD: Office of the Center Director

Meeting Summary

Following introductions, and FDA's opening remarks, the following topics were discussed:

Overall aim of COSMIIC and need for Right-of-Reference to a Master File
The CWRU team explained the goal of trying to remove barriers to researchers trying to develop implantable devices. The goal of the blanket right-of-reference (RoR) letter was an attempt to minimize hurdles to access to the information in the Master File (MAF). This also relates to the project's sustainability, as it removes a layer of gatekeeping between the researcher and access to the information. FDA explained it would be possible to have a RoR to a concluded IDE. However, FDA is not comfortable with the Q-Sub sponsor (COSMIIC, Inc.)'s proposed use of a blanket RoR letter to provide *a priori* authorization for *any* IDE sponsor to leverage the MAF's contents without COSMIIC Inc.'s knowledge, for the reasons detailed in the written feedback provided before the meeting. Specifically, it is important for COSMIIC, Inc. to maintain traceability of who is using the MAF so that it can communicate future changes to the MAF to IDE sponsors who reference the MAF in their approved IDE studies.

How MAF and RoR Typically Work
FDA explained that typically questions go to the MAF holder because the MAF itself is confidential, and the entity with the RoR would not know what is in the MAF. However, since we are making the MAF open access, the questions could go to either the MAF holder (COSMIIC, Inc.) or to the IDE investigator. There can be flexibility as to which entity receives FDA's questions, and that can be explained either in the IDE application, or in the RoR letter. To ensure that review-related communications are appropriately routed for each IDE that references the MAF, FDA recommends that the MAF contain a note that the permission to receive MAF-related review questions and to view the MAF contents will be specified in the RoR letter and IDE submission (as applicable) for each IDE that references the MAF. If the MAF gets updated, prior holders of a RoR would not necessarily automatically have a right to reference the new material unless the RoR stated that the holder of the RoR could reference the Master File and all subsequent amendments. If the RoR only states that the original Master File can be referenced, a new RoR letter would be needed to enable the IDE investigator reference subsequent MAF amendments. ~~; rather, a case could then be made for establishing why the new information is relevant to the RoR holder's specific application via IDE supplement.~~ In either case, an IDE supplement would be needed for IDE sponsors to obtain FDA approval to incorporate new information in the updated MAF (e.g. changes to the device design or manufacturing) for each IDE study that wishes to incorporate these updates.

MAUDE Database as a Repository for Adverse Event Information in IDE's
FDA explained that the database is not designed for investigational devices; a product code is typically needed. In response to the sponsor question, it was explained that the idea of a temporary product code for the investigational device was brought forth internally but not accepted as a solution. The MAUDE database feeds into a post-market medical device reporting (MDR) review stream that is not suitable for reviewing IDE adverse event (AE) information, and ~~our~~the submission of such information would complicate the~~at~~ MDR review process. FDA said it was

open to creative thinking on this topic, but that no ready solution appears at this point. FDA reminded the sponsor that each investigator will have to report AE's under their IDE, per the standard IDE adverse event evaluation and reporting requirements under 21 CFR 812.46 and 21 CFR 812.150. NIH attendee Dr. Gross suggested it might be possible for the NIH SPARC platform to serve this role, because it is open to the public now. A concern was raised that collecting adverse event information is "delicate" in that it requires attention not to reveal private health information. If the COSMIIC project can't find an adequate way to share information across research teams, it will then fall on the FDA to be the only entity that can synthesize disparate events across the user community, as no group would be able to see the events of other groups. There was discussion about the possibility of COSMIIC, Inc. creating a "MAUDE-like" database for the COSMIIC community's use, that used the same intake form.

Role of COSMIIC, Inc

In response to an FDA question about the ongoing role of COSMIIC, Inc. and whether it will continue to serve as the investigational device manufacturer, the sponsor explained that COSMIIC, Inc, is intended to be a small company with minimal responsibilities. It would serve as the manufacturer of record, and also "curate" amendments to the MAF.

Role of FDA in the COSMIIC community

The sponsor explained that in the online community forum, it would be an added benefit if FDA contributed to the ongoing conversation, understanding that it is "voluntary" and not the official mechanism for interacting with the agency.

Biocompatibility

The sponsor stated that it will continue to absorb FDA's feedback on this point and may further address the biocompatibility information for the subject device in a future Q-Submission, or in future updates to the MAF.