From:	Jeff Goehring
To:	Covid19PrioritizedExamPilot; Clarke, Robert (DCPEP)
Cc:	*[REDACTED]*
Subject:	comment and question regarding the COVID prioritized examination pilot program
Date:	Friday, May 15, 2020 11:07:05 AM

Hello,

This is a comment and question regarding the COVID prioritized examination pilot program.

It is not very clear what it means for an application to "cover" a product or process "relating" to COVID-19 such that the product or process "is subject to an applicable FDA approval for COVID-19 use."

The PTO Notice says that such approvals "may include, but are not limited to" an Investigational New Drug (IND) application, an Investigational Device Exemption (IDE), a New Drug Application (NDA), a Biologics License Application (BLA), a Premarket Approval (PMA), or an Emergency Use Authorization (EUA).

My question is does the "subject to an applicable FDA approval for COVID-19 use" include the FDA regulation of Class I and II medical devices through 510K submissions and/or through the *de novo* classification process?

Best Regards,

Jeff Goehring
[phone & email redacted]