

APPROVED

By Jean Gildner at 2:26 pm, Jul 19, 2016

From: [Margarita Aguilera](#)
To: [Yao, Michael \(CBER\)](#)
Cc: [Schneider, Bruce](#); [Gildner, Jean](#)
Subject: Request for additional clinical information
Date: Wednesday, June 15, 2016 4:57:18 PM
Attachments: [Response to FDA Information Request dated 13June2016.pdf](#)

Dear Dr. Yao,

Attached please find responses to the questions raised in your Request for Additional Clinical Information email dated 13 June 2016.

Please let me know if additional information or clarification is needed.

Kind Regards,
Margarita

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From: Yao, Michael (CBER) [<mailto:Michael.Yao@fda.hhs.gov>]
Sent: Monday, June 13, 2016 4:48 PM
To: Margarita Aguilera
Cc: Schneider, Bruce; Gildner, Jean; Yao, Michael (CBER)
Subject: request for additional clinical information
Importance: High

Hi Margarita,

Regarding MACI implant procedure, I have following questions regarding use of Fibrin sealant for fixation of MACI implant during procedure:

1. In the surgeon manual, you did not provide following information regarding use of Fibrin sealant:

- a. Which brand of Fibrin sealant (by manufacture) had been used in SUMMIT study?
- b. Please provide justification for the dose and variability of Fibrin sealant in SUMMIT if multiple brands of Fibrin sealants (by manufactures) were used in SUMMIT study.
- c. What dose range of Fibrin sealant were applied in SUMMIT study.

2. Any AEs or SAEs related to use of Fibrin sealants in SUMMIT study?

Thanks.

Michael