

From: Do, Yu
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Thursday, April 13, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Tuesday, April 04, 2017 9:32:00 AM
Attachments: [image001.png](#)
Importance: High

Dear Ms. Robertson:

We are reviewing your original November 3, 2016, submission to BLA 125640 for Fibrin Sealant (Human). We determined that the following information is necessary to continue our review:

As a follow-up to the interviews conducted during the pre-license inspection of your facility, please submit to this BLA the current versions of the following reports related to the Design History File:

- IG_ITEC-002800_ING: Fibrin Sealant Grifols. Traceability Matrix (dated February 10, 2017)
- IG_ITEC-002568_ING: Viability and Functionality of the Fibrin Sealant Grifols application device (dated October 03, 2016, or its latest version)
- IG_ITEC-001403_ING: Fibrin Sealant. Application tests depending on the type of cannula (dated May 10, 2012, or its latest version)
- IG_ITEC-002747_ING: Fibrin Sealant. Usability (dated December 23, 2016)
- IG_ITEC-002779_ING: Fibrin Sealant. Usability (dated February 03, 2017)
- IG_MSP-002046_ING: Medical Device Design History File (dated February 07, 2017)
- IG_ITEC-002783_ING: Fibrin Sealant Grifols Kit: Overall Design Plan (dated February 06, 2017)

If any of these reports have already been submitted, please specify their respective number and date of the amendment(s) and eCTD section(s).

The review of this submission is ongoing, and issues may be added, expanded upon, or modified as we continue to review this submission. Please submit your response as an amendment to this file by April 13, 2017, referencing the date of this request, together with the response to Information Request dated March 30, 2017. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is November 3, 2017.

Please acknowledge receipt of this request and contact me at (240) 402-8343 or

Yu.Do@fda.hhs.gov if you have any questions.

Sincerely,

Yu Do, M.S.
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