

From: [Do, Yu](#)
To: Joan.robertson@grifols.com
Subject: Information Request (Response Due by Thursday, October 5, 2017): Original BLA, BL 125640/0, Fibrin Sealant (Human), Instituto Grifols, S.A.
Date: Tuesday, September 26, 2017 9:59:00 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 have the following comment and requests for additional information to continue our review:

The main objective of Preliminary Part (I) of each of the three Phase 3 trials was to ensure that study teams become familiarized with the technique for FS Grifols application.

Please describe the procedural protocol that was used in Part (I) to train investigators/study personnel and include data pertaining to how easy/difficult it was to assemble the device. Please also provide the reported success/failure data in regard to ease/difficulty of applying the study agents to study target sites with the assembled device during Part (I) of the studies.

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 October 5, 2017, referencing the date of this request. 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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