DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134 Industry Information: www.fda.gov/oc/industry	05/26/2015 - 06/17/2015* FEI NUMBER 2183620

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Scott P. Bliss, Plant Manager

FIRM NAME	STREET ADDRESS
Synovis Life Technologies, Inc. (sub. of Baxter Int'l, Inc.)	2575 University Ave W
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Paul, MN 55114-1073	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically, corrective and preventive actions were not initiated when procedures required and potential nonconformities were identified and evaluated outside the CAPA system. Corrective and Preventive Action Procedure, SP-1161, Rev V states a CAPA request shall be submitted if recurring nonconformities are identified in Management Reviews and other trend reviews and also requires evaluation to assess the impact and risk of the existing or potential nonconformities. From 03/30/2015- 04/10/2015 you identified multiple potential nonconformities for the same product and failure mode through your complaint handling system. Users were unable to determine the rough vs. smooth side of the Terminally Sterilized Vascu-Guard patch, as both appeared to be rough. Many users declined to use the product in procedures because of this.

- You determined these complaints were collectively significant enough to address via a Frequently Asked Questions (FAQ) document, which was sent to the field on 4/10/2015 and used by sales reps in the field to address these types of possible nonconformities. After identifying these recurring possible nonconformities, you did not initiate a CAPA to investigate or evaluate their risk within your CAPA system and there is no formal process for the FAQ within the quality system.

- In addition, you initiated health hazard analysis and medical/risk assessment activities on 04/09/15 with your medical staff for the potential rough/smooth issue, but did not do this within your CAPA system as your procedure requires. CAPA #874740, for this issue, was not initiated until 04/30/2015, after an adverse event was logged (04/23/2015) and after determining all complaints for this failure code are reportable (04/27/2015).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kyle J. McCracken, Investigator	06/17/2015

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OBSERVATION 2

Complaints involving the possible failure of a device to meet any of its specifications were not evaluated and investigated where necessary.

Specifically, there were 26 complaints reviewed during the inspection which were not reviewed, evaluated, and escalated in a uniform manner or did not follow your complaint investigation procedure (SP-1841, Rev D). SSI Complaint Investigation SP-1841, Rev D requires QAE investigators to review the applicable risk assessments to determine if the failure mode reported by the customer is addressed in risk assessment, including the occurrence rate, and record the risk assessment number, revision, and line items that address the failure mode, and justify whether an update is needed.

- Complaint investigations failed to evaluate and escalate that the complaint rate exceeds the expected occurrence rate in the Use-Misuse FMEA regarding physicians-not being able to differentiate rough side from smooth side in Terminally Sterilized Tissue Guard.
- You received multiple complaints stating both sides of Terminally Sterilized Tissue Guard appeared or were "rough", which was not a potential failure mode identified in your design risk analysis documents (FMEA) and your complaint investigations did not properly review, evaluate, and escalate these reported potential nonconformities using risk documents as required by the procedure (SP-1841).

OBSERVATION 3

Design validation did not ensure the device conforms to defined user needs and intended uses.

Specifically, there is no specification smoothness (or roughness) for the Tissue Guard product family and studies conducted prior to market release for Terminally Sterilized Tissue Guard did not fully address smoothness/roughness attributes to ensure all risks were mitigated.

The Instructions for Use for Terminally Sterilized Tissue Guard instruct the physician to examine the patch and if one side appears smoother, implant the smooth side toward the vascular surface (down).

Potential failure modes identified in your Use/Misuse FMEA established that tissue can be manufactured and released in a way that the rough side of the patch, if implanted towards the vascular surface, could cause permanent impairment or life threatening injury, which is a critical failure. The Use/Misuse FMEA also identifies the occurrence of physicians/users not being able to identify smooth vs. rough side was probable. (b) (4)to (b) (4)

The validation studies conducted prior to market release did not address smoothness/roughness attributes of both sides of the tissue to ensure the design met user needs and intended uses.

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Observation Annotations

Observation 1: Promised to correct.
Observation 2: Promised to correct.
Observation 3: Promised to correct.

*** DATES OF INSPECTION:**
05/26/2015(Tue), 05/27/2015(Wed), 05/29/2015(Fri), 06/03/2015(Wed), 06/04/2015(Thu), 06/08/2015(Mon), 06/09/2015(Tue), 06/11/2015(Thu), 06/17/2015(Wed)

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	Kyle J. McCracken, Investigator	06/17/2015