DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	2/9/2026-2/18/2026*
	FEI NUMBER 3009809074

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alpesh Patel, Senior Vice President of Regulatory Affairs and Quality

FIRM NAME	STREET ADDRESS
BioTissue Holdings Inc	8305 Nw 27th St Ste 101
CITY, STATE, ZIP CODE, COUNTRY Doral, FL 33122-1934	TYPE ESTABLISHMENT INSPECTED 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

An MDR report was not submitted within [redacted] of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically,

Your firm received a complaint number [redacted] where the patient had increased pain and photophobia at the time of a scheduled appointment. Exam noted subconjunctival hemorrhage around the eye, more concentrated inferiorly where the device ring had sat on the eye. The eye appeared chemotic with brown/yellow discharge and the eye appeared blood red. Scattered SPK was noted on [redacted] visit. The Prokera device was removed. The patient was prescribed Maxitrol (antibiotic/steroid combination ointment) to be applied 4x daily for 1 week. Signs and symptoms improved with pain relieved and chemosis resolved by [redacted]. Redness, itching and increased intraocular pressure noted on [redacted] but patient continues to be improving. In addition to Maxitrol, the patient was prescribed Systane Pro preservative free eye drops 2-4x daily, artificial serum tears (AST) 40% 2-6% and cold compress with ibuprofen for pain. The firm conducted an Adverse Event Evaluation Form, [redacted] where it is documented that the event is not reportable, and this type of reaction is expected.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ronald Ifraimov, Investigator	X Ronald Ifraimov Investigator Signed By: Ronald Ifraimov -S Date Signed: 02-18-2026 09:40:49	2/18/2026

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The firm received a complaint number [redacted] where the patient reported having discharge in the left eye as well as pain on [redacted] Upon device removal, the doctor noted anterior chamber inflammation. Culture was obtained, which returned a negative result. Device was removed and patient was noted to be better after removal. Patient was treated with prednisolone drops 4x daily and moxifloxacin 4x daily. She is now improved without anterior chamber cells (inflammation resolved). Has reduced prednisolone to 2x daily and is continuing treatment for dry eye syndrome with other therapies. The firm conducted an Adverse Event Evaluation Form, [redacted] where it is documented that the event is not reportable, and this type of reaction is expected.

The firm received a complaint number [redacted] where the Prokera SLIM was placed on [redacted] and the patient tolerated it well overnight. Patients Diagnosis is DED. On [redacted] the patient presented to the clinic without an appointment, showing significant bleeding in the eye where the device had been placed. Dr. removed the PKS and noted that the AMT was still intact on the ring, but the entire device was covered in blood, with red blood oozing from the eye. It appeared to be a conjunctiva! laceration. Dr. cleaned the area and applied gauze and tape. Dr. then evaluated the patient on [redacted] where she reported improvement with "no significant injury." During a follow-up visit on [redacted] Dr. noted a slight decrease in visual acuity in that eye compared to the preProkera placement on [redacted] The firm conducted an Adverse Event Evaluation Form, [redacted] where it is documented that the event is not reportable, and this type of reaction is expected.

This observation is a repeat observation from the previous inspection date 3/6/2024.

OBSERVATION 2

Information gathered in the feedback process does not adequately serve as potential input into risk management for monitoring and maintaining product requirements as well as the product realization or improvement processes.

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Your firm received approximately 14 complaints where patients were experiencing pain and were administered prescription drugs such as steroids and antibiotics.

During the review of the firms D/UFMEA-001 for Prokera Slim and Prokera Clear as well as D/UFMEA-002 for Prokera Classic and Prokera Plus the firm did not identify "Pain" as a risk factor. The firm also uses a Risk Analysis Harms-Severity Cross Reference document number APPEX-0138, Revision 05. Risk Analysis Harms-Severity Cross Reference document does not identify "Pain" as a risk factor or "severity" where prescription medication is necessary to treat pain.

OBSERVATION 3

Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence.

Specifically,

Your firm maintains a document called Summary Memo: Complaint Metrics Monitoring and Escalation Process where the firm summarizes the process for monitoring complaint data, including how to use control charts to identify potential trends and how we escalate those trends to the CAPA system when appropriate. This document does not note any criteria used to determine if a CAPA is necessary.

During the inspection, it was noted that the firm received approximately 95 complaints from April 2025 to December 2025. Of those complaints, the firm received 14 complaints for pain, 6 with broken band, 8 for un-clipping, and 5 torn. CAPA was not opened to address these complaints.

***DATES OF INSPECTION**

2/09/2026(Mon), 2/10/2026(Tue), 2/12/2026(Thu), 2/18/2026(Wed)

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Annotations to Observations

Observation 1: Under consideration

Observation 2: Under consideration

Observation 3: Under consideration

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."