DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608 2900 Fax:(949) 608 4417 Industry Information: www.fda.gov/oc/industry	05/27/2015 06/16/2015* FEI NUMBER 3002942014

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Giora (nmi) Fishman, Executive Vice President

FIRM NAME	STREET ADDRESS
PhotoMedex, Inc.	2375 Camino Vida Roble Ste B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Carlsbad, CA 92011 1556	Medical Device 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 WE OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days 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, complaint CC-XMR-0495 created on 10/31/2014 alleges that a patient was treated on Tuesday at 1:00pm, by 5:00 pm that night she felt extremely sunburned on her lower legs, mostly shins that had been treated. She went to the ER where they tried a lidocaine salve but it was too painful to apply. They gave her morphine. The dermatologist stated that they used the lowest dose and has never seen anyone react that way. The firm determined this case to be an isolated case of a patient with extreme sensitivity to XTRAC treatments and that the patient's experience does not meet the definition of serious injury and is therefore not a reportable event. An MDR was not filed for this complaint.

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, complaint CC-XMR-0592 created on 03/12/2015 alleges that the LLG is firing on its own and the customer was requesting a new one. The LLG was returned under RMA 1764. Engineering and Test Evaluation findings showed during the visual inspection a slight bend in LLG, nylon sleeve fraying, input damaged, and a dirty shield. The engineers could not replicate the complaint and the (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shaquenta Y. Perkins, Investigator Scott K. Zika, Investigator	06/16/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608 4417 Industry Information: www.fda.gov/oc/industry	05/27/2015 06/16/2015* FEI NUMBER 3002942014

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Giora (nmi) Fishman, Executive Vice President

FIRM NAME	STREET ADDRESS
PhotoMedex, Inc.	2375 Camino Vida Roble Ste B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Carlsbad, CA 92011 1556	Medical Device Manufacturer

(b) (4) . An MDR was not filed for this complaint.

OBSERVATION 3

Risk analysis is inadequate.

Specifically, the firm's risk management procedure, SOP-0024 titled, "Risk Management," Revisions A-C, section 6.3.7 requires complaints to be evaluated for post market risk. However, the following example demonstrates this requirement was not followed: From 03/01/2014 to 06/11/2015, the firm has received approximately 41 complaints associated with the LLG component of the XTRAC laser family of devices. 19 of the 41 complaints and/or 46% (19/41 = 46%) are further associated with the failure allegations of intermittent (7), not firing (6), trigger cable not in specification (3), and needs to be held in a certain way (3) (7 + 6 + 3 + 3 = 19). These complaints were not evaluated as a newly determine health risk (i.e., the firm did not update their risk analysis to include a bent, breaking or damaged LLG wire, post calibration of the LLG, which resulted in allegations of intermittent firing, misfiring, or not firing events.

OBSERVATION 4

Procedures for design change have not been adequately established.

Specifically, the firm did not perform validation and/or verification activities associated with the following changes to their Liquid Light Guide (LLG) touch control assemblies:

a) ECO 3233 was opened on 08/04/2009 (and closed on 10/07/2009 under ECO 3252) to change the design to prevent (b) (4) (b) (4) The change was to (b) (4) The firm determined that the (b) (4) (b) (4) The firm checked "No" in their evaluation of "is qualification/validation required." Also, there was no justification as to why this change did not require validation and/or verification.

b) ECO 3437 was opened on 03/07/2011 (and closed on 05/11/2011) to (b) (4) . In addition (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shaquenta Y. Perkins, Investigator SYP Scott K. Zika, Investigator	06/16/2015

(b) (4) The firm checked "No" in their evaluation of "is qualification/validation required." Also, there was no justification as to why this change did not require validation and/or verification.

c) ECO 3524 was opened on 10/18/2011 (and closed on 10/27/2011) to (b) (4). The firm checked "No" in their evaluation of "is qualification/validation required." Also, there was no justification as to why this change did not require validation and/or verification.

d) ECO 3761 was opened on 08/27/2013 (and closed on 09/03/2013) to modify the design of the (b) (4) (b) (4). The firm checked "No" in their evaluation of "is qualification/validation required." Also, there was no justification as to why this change did not require validation and/or verification.

Furthermore, neither the firm's work instruction procedure for changes titled, WI-0001-A "Engineering Change Order Process" nor the firm's form AF-0006 "Engineering Change Order and Distribution Form" require a regulatory assessment.

OBSERVATION 5

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

Specifically,

a) The firm's procedure for establishing trends, SOP-0029, titled "Statistical Techniques and Trending," Revision A, does not define what statistical methods are to be used to determine if an adverse trend has occurred.

Furthermore, the firm has not established any complaint trend and/or component trigger points to provide quantifiable guidance in determining when corrective and/or preventive actions are required (i.e. no thre have been established).

b) The scope of corrective action associated with CAPA Report 14-01, dated 01/31/2014 is inadequate because it only evaluated field service information (for complaint and/ or MDR reporting) dating back to 01/2013. However, from 05/2009 through 09/2011, the firm has on file approximately 168 Return Material Authorization (RMA) reports, which also were not evaluated for complaint and/or MDR reporting. Table 1 below provides a sample of the 168 reports that were not evaluated:

Table 1 - RMAs not Evaluated for Complaint and/or MDR Reporting

RMA Number	Date	Part No.	Allegation
5209	12/03/2010	01-08529-01	TC-Intermittent
5273	02/01/2011	01-08529 01	TC not working
5336	03/07/2011	01-08571-01	TC-Intermittent
5399	04/14/2011	01-08529-01	E53*
5504	07/15/2011	01-08529-01	0% T**
5596	08/12/2011	01-08529-01	misfiring

*E53 - Sensor Ratio Less than 40%
**0% Transmission

OBSERVATION 6

Procedures for finished device acceptance have not been adequately established.

Specifically, the firm's finished device acceptance procedure, SOP-0008, titled "Release of Materials: Components and Final Product," Revisions A-C, have not been defined and documented to ensure that finished devices were made in accordance with the specifications required by the Device Master Record. There are no final verification acceptance activities to address trigger cable length and critical

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608 2900 Fax:(949) 608 4417 Industry Information: www.fda.gov/oc/industry	05/27/2015 06/16/2015* FEI NUMBER 3002942014

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Giora (nmi) Fishman, Executive Vice President

FIRM NAME	STREET ADDRESS
PhotoMedex, Inc.	2375 Camino Vida Roble Ste B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Carlsbad, CA 92011 1556	Medical Device Manufacturer

dimensions. For example:

a. LLG Serial Number 05-42340 was returned to the firm on 01/27/2015, under Return Material Authorization (RMA) 1623, for allegedly being very difficult to fire. Findings from RMA 1623 showed during the visual inspection that there was a missing screw in the hand piece, foam spring was not centered, and critical dimensions were not in specification. The LLG was authorized by quality to be released on 11/08/2012 via DHR 42340-A.

b. LLG Serial Number 42-43139 was returned to the firm on 08/14/2014, under RMA 1062, for the allegation of current LLG keeps jamming. Findings from RMA1062 showed a bend in the LLG and trigger cable length not within specification. The LLG was authorized by quality to be released on 03/07/2013 via DHR 43139-E.

c. LLG Serial Number 16-47441 was returned to the firm on 02/25/2014, under RMA-XMR-0521, for the allegation of firing intermittently. Findings from RMA-XMR-0521 found that the LLG Strain Relief had a defective electrical connector in addition the length of the electrical cable was not to specification. The LLG was authorized by quality to be released on 02/14/2014 via DHR 47441.

Observation Annotations

Observation 1: Promised to correct by 6/26/2015.
Observation 2: Promised to correct 06/30/2015.
Observation 3: Promised to correct by 07/31/2015.
Observation 4: Promised to correct within 60 days.
Observation 5: Promised to correct within 90 days.
Observation 6: Promised to correct within 60 days.

*** DATES OF INSPECTION:**
05/27/2015(Wed), 05/28/2015(Thu), 06/01/2015(Mon), 06/02/2015(Tue), 06/09/2015(Tue), 06/10/2015(Wed), 06/16/2015(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shaquenta Y. Perkins, Investigator Scott K. Zika, Investigator	06/16/2015

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 judgement, 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."