DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	6/1/2016-6/3/2016 FEI NUMBER 3004786509

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Charles H. Payne , Vice President (VP) of Product Development & Manufacturing

FIRM NAME	STREET ADDRESS
InterX Technologies	870 N Dorothy Dr, Ste 708
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Richardson, TX 75081	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 I OBSERVED:

OBSERVATION 1

Procedures for design change have not been adequately established.

Specifically, your Product Development Doc. # SOP-011 (Rev. D) states "Changes to existing products or previously released documents shall use WP-039 (ECN processing and approval) as the guiding procedure."

On 6/2/2016, my review of your NCMR # NC14MAY2101, dated 5/21/2014, revealed an extreme bond force between the (b) (4) and blue liner for your sterile, cutaneous gel electrodes. Due to the strong bond to the liner, the gel was pulling away from the carbon layer when the liner was removed. Upon evaluation by your contract manufacturer, it was noted that the (b) (4) had a tendency to peel away from the carbon film in a couple areas as the liner was removed. Further investigation by the manufacturer found that since the production of this lot (i.e., ISSDE Product Lot # 318386), there had been a change to the liner used. This changed the (b) (4). This change was made in order to relieve processing difficulties as well as produce a more consistently performing liner. A corrective action was taken in changing the liner on or around October 2014.

I observed no ECN processing and/or approval per WP-039 as part of your design change control to the liner for the ISSDE sterile, hydrogel electrode device products. Without fully understanding the change made to the liner and how the release strength of the liner to the gel was newly characterized, you still

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	Leighton K Ngai, Investigator 6/3/2016 X Leighton K Ngai Leighton K Ngai Investigator Signed by: Leighton K. Ngai -S	6/3/2016

commercially distributed the products as evidenced by your shipments to customers in November 2014 and March 2015.

OBSERVATION 2
Procedures for design validation have not been adequately established.

Specifically, your Product Development Doc. # SOP-011 (Rev. D) defines "Design Validation: Establishing by objective evidence that device specifications conform to user needs and intended use(s)."

On 6/2/2016, I observed your design validation records, dated September 2006, documented that the InterX™ 1000 and InterX™ Personal Sport handheld devices were validated by individuals with clinical expertise such as clinical specialists and physical therapists for delivering substantially equivalent stimulation as well as providing the same clinical outcomes as predicate devices, but there appeared to be no objective evidence of the experts' validation.

OBSERVATION 3
The design verification results, including identification of the design and method(s) , were not adequately documented in the design history file.

Specifically,

1. On 6/2/2016, I observed information from your System/Software Safety Test Report Doc. # RPT-013 (Rev. A, dated 9/19/2006) conflicted with information from your System/Software Safety Test Protocol Doc. # PRT-013 (Rev. 1.0, dated 8/2/2006) for the InterX™ Personal device line, which is inclusive of the Personal Sport and 1000 models.

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Doc. RPT-013 described the following results from the System/Software Safety Test Protocol, PRT-013, and/or test activity as follows to indicate final test results after all testing, including any regression tests:

(Section/Title) Summary	**Results Summary**
2.1 ELECTRODE HANDLING: Tests to assess proper handling of external electrodes	All test steps passed with no variances or deviations.
2.3 SIMULTANEOUS KEY PRESSES: Tests to assess reaction to simultaneous key presses.	All test steps passed with no variances or deviations.

Although regression tests indicated all test steps passed, I observed variances and/or deviations for certain test steps conducted in the initial test cases prior to regression testing. For example, Doc. PRT-013 reported actual results of Fail for one observation as well as two problems identified in Steps (b) (4) of the (b) (4) Electrode Handling test case. Additionally, Doc. PRT-013 reported an actual result of Fail for one problem identified in Step (b) (4) of the (b) (4) Simultaneous Key Presses test case. The Fail results were not accounted for as variances/anomalies in your design verification test summary for the InterX™ Personal Devices.

2. On 6/3/2016, I observed information from your System Design Test Report Doc. # RPT-009 (Rev. A, dated 9/19/2006) conflicted with information from your System Design Verification Protocol Doc. # PRT-009 (Rev. 1.0, dated 8/2/2006) for the InterX™ Personal model devices (i.e., InterX™ Personal Sport and InterX™ 1000).

   Doc. RPT-009 described the following specification change issue noted in the (b) (4) Switches test case to assess design and implementation of external switches: "The original requirement indicated that switches would have no more than a (b) (4)% probability of failure for (b) (4) operations. Subsequent to release of the protocol, the Change Control Board agreed to change this to (b) (4) operations. The specification was changed via ECN 383, verified by evaluating the manufacturing specifications, and the test was marked as a PASS."

However, Doc. PRT-009 reported "Subsequent to the protocol being released, the specification was changed from (b) (4) operations to (b) (4) operations". I observed Steps (b) (4) of the (b) (4) Switches test case were redlined to (b) (4) and not (b) (4) operations as stated in your design verification test summary for the InterX™ Personal Devices.

OBSERVATION 4
Procedures for design review have not been adequately established.

Specifically, your Design Review Work Procedure Doc. # WP092 (Rev. C) states "Key personnel must be present and shall represent the functions under review. At least one reviewer shall be present who does not have responsibility for the design."

On 6/2/2016, I observed your Design Review Record Form FRM-WP007-03 (Rev. A), dated 9/27/2006, for the design transfer phase of the InterX™ Personal 1000 device lacked an attendee who was independent of the design stage (i.e., design transfer) being reviewed.

OBSERVATION 5
Procedures for corrective and preventive action have not been adequately established.

Specifically, your CAPA Doc. # SOP-023 (Rev. D) states a corrective action will be initiated for any identified nonconformities, and nonconforming material investigations are documented on an NCMR per your Control of Nonconforming Product Doc. # SOP-022 (Rev. C). You have documented nine nonconformities in 2014 and four nonconformities in 2015. These nonconformance investigations involve critical suppliers. The nonconformities include, but are not limited to, brittle plastic caps, contaminated switches, bag mislabeling, back nut/outer shell locking threads not fitting, conformal coating on the center switch, broken device icon, missing back plates for comb electrode caps, missing LED at top housing, and intermittent power-up issue. Five out of nine nonconformities from 2014 and two out of four nonconformities in 2015 are still awaiting disposition. You are still waiting for supplier information for closure of the open nonconformities.

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For instance, on 6/2/2016, I observed your tactile switch contamination nonconformance (NCMR # NC14MAR1201, dated 3/12/2014), red vertical line on OLED display nonconformance (NCMR # NC14AUG1401, dated 8/14/2014), and conformal coat in switch nonconformance (NCMR # NC14OCT2101, dated 10/21/2014) lack follow-up verification plus validation activities for the documented CAPAs to ensure that the actions are effective in achieving the desired effect and does not result in other adverse effects as required by SOP-023.

Annotations to Observations

Observation 1: Promised to correct
Observation 2: Promised to correct
Observation 3: Promised to correct
Observation 4: Promised to correct
Observation 5: Promised to correct

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SEE REVERSE OF THIS PAGE	Leighton K Ngai, Investigator	6/3/2016 X Leighton K Ngai Leighton K Ngai Investigator Signed by: Leighton K. Ngai -S	6/3/2016

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."