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# News Update

## **US FDA Inspection Reveals Excite Medical Does Not Own 510(k) Clearances for any DRX System**

**March 26, 2013, Tampa, Florida, USA.** Axiom Worldwide, Inc. has verified through official correspondence from the United States Food and Drug Administration that neither Excite Medical in Tampa, Florida or HTRD Group in Hong Kong own any 510(k) clearances for any DRX system. This determination by the FDA in a July 2012 Establishment Inspection Report (EIR) appears to be in direct conflict with the various press releases issued by Mr. Saleem Musallam and Ms. Livia Fernandes of Excite Medical, and Mr. David Ren of China and HTRD Group of Hong Kong. This documentation further exposes the fraud these parties continue to commit with respect to Axiom's Intellectual Property.

In Axiom's ongoing efforts to provide up to date and accurate information to the global healthcare community, an official Freedom of Information Act (FOIA) request was submitted to the FDA for all correspondence relating to Excite Medical's compliance with FDA regulations and requirements. Included in the FDA's response to the FOIA request as the July 2012 FDA Establishment Inspection Report (EIR) that not only highlighted the deficiencies in Excite's Quality Systems, but more importantly identified a glaring fallacy contained in their marketing communications.

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The EIR listed two specific statements by the US FDA Federal Investigators regarding the existence of any 510(k) clearances for Excite Medical and/or HTRD Group:

***“We searched the FDA 510(k) Premarket Notification website and could not find any 510(k)s registered to Excite Medical Corp.” (#1 - See Attached EIR)***

***“Our search of 510(k) submissions did not show any 510(k)s associated with Excite Medical Corp or HTRD Group Hong Kong, Ltd. for the DRX5000 and DRX9000 devices assembled by Excite Medical.” (#2 - See Attached EIR)***

However, a March 31, 2011 Press Release issued by Ms. Livia Fernandes, Vice President of Excite Medical, states that in December 2010 ***“The United States Food and Drug Administration transferred legal ownership of the (Axiom) 510(k)s.”***(#3 - See Attached Press Release). To date there is no verified documentation to suggest that there was a valid transfer of Axiom's Inc. 510(k)s to Excite Medical or HTRD. In essence, without either a valid submission or evidence of a legal transfer of a 510(k), then it may be a violation of federal law for anyone to manufacture, market and sell such a device.

Because these devices can potentially be considered adulterated and illegal, the FDA has the authority to subject any medical devices determined to be illegal to recall. If you are considering purchasing or have purchased a potentially illegal DRX since April of 2010, consider confirming the legal owner of the 510(k) clearances and contact the US FDA directly before putting your patients at risk.

In July 2011, Axiom Worldwide, Inc., filed its Verified Complaint seeking declaratory and injunctive relief as well as damages as against Defendants - HTRD Group Hong Kong Limited a/k/a HTRD Group Hong Kong Limited, Inc. (HTRD); Ryzur Medical, Inc., Ryzur Medical Group; Ryzur Medical Investment Co., Ltd.; Excite Medical Corp. (Excite); Excite Diagnostics, LLC; Eltech USA, LLC; David Ren; Saleem N. Musallam; and Andrew Deweerd (collectively "Defendants") for alleged trademark and copyright misappropriation and infringement, unfair competition, breach of confidentiality agreements, providing false information to the USPTO, and interference with business relationships. The defendants filed false documents with the US Patent and Trademark Office and the US FDA, and other US and foreign government agencies in an attempt to fraudulently benefit, assign and utilize Axiom's trademarks and intellectual property

illegally. In Axiom's opinion, all of these acts have been illegal and harmful to Axiom and now it appears the courts are in agreement with Axiom.

Axiom Worldwide, Inc was founded by Mr. James Gibson in 2001 in Tampa, Florida and obtained multiple US FDA 510(k) clearances over the years. Axiom invented its flagship product the DRX9000 True Non-surgical Spinal Decompression System and the DRX9000C for use in medical markets around the globe. The DRX 9000 and the DRX9000 C were created to provide relief of back and neck pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome, and sciatica.

Please contact Mr. James Gibson, President and CEO of Axiom Worldwide, Inc for more information at [President@AxiomWorldWide.com](mailto:President@AxiomWorldWide.com). For more news updates, visit [www.AxiomWorldWide.com](http://www.AxiomWorldWide.com) and click on the News Link.

**Establishment Inspection Report**

Excite Medical Corp  
 Northdale, FL 33624

FEI: 3008816697  
 EI Start: 07/24/2012  
 EI End: 07/25/2012

- The firm's Quality System procedures failed to include original equipment manufacturer approvals, investigations, corrective actions, and all quality analyses for the firm's device.
- The firm failed to insure that internal audits were performed by persons with no responsibility for the area audited as required by the firm's Internal Quality Audits procedure.

We covered the following Subsystems: Management Controls; Corrective and Preventive Actions; Design Controls; and Production and Process Controls.

#1

Excite Medical Corp is currently registered as a medical device contract manufacturer. We searched the FDA 510(k) Premarket Notification website and could not find any 510(k)s registered to Excite Medical Corp. <sup>1</sup>

**ADMINISTRATIVE DATA**

Inspected firm:	Excite Medical Corp	
Location:	5555 West Linebaugh Avenue Suite M Northdale, FL 33624	
Phone:	813-210-1000	
FAX:	888-408-0407	
Mailing address:	5555 West Linebaugh Avenue Suite M Northdale, FL 33624	
Website:	<a href="http://excitemedical.com/">http://excitemedical.com/</a>	
Email	Saleem N. Musallam, President	SM@ExciteMedical.com
	Livia Fernandes, Vice President	livia@ExciteMedical.com
Dates of inspection:	7/24/2012, 7/25/2012	
Days in the facility:	2	
Participants:	Jason P. Aun, Investigator Leo J. Lagrotte, Investigator	

**HISTORY**

Mr. Saleem N. Musallam, President stated that Excite Medical Corp was incorporated in State of Florida on 12/17/2007 and started selling finished devices in 2011. Mr. Musallam stated that a firm formerly known as Axiom Worldwide, Inc. previously held the 510(k)s (K023160 and K060735) used to make the same devices currently made by Excite Medical Corp.

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1. [REDACTED]
2. Mr. Musallam stated that Axiom Worldwide, LLC's assets were purchased in 2010 by HTRD Group Hong Kong, Ltd. (FEI: 3009627959), located in China and in that same year Excite Medical partnered with HTRD to produce the two spinal decompression traction devices DRX5000 and DRX9000.
3. The Florida Department of State Division of Corporations website shows that:
  - a. Axiom Worldwide, Inc. and Axiom Worldwide, LLC are two separate entities
  - b. Axiom Worldwide, Inc. is still listed as an active corporation (**Attachment 5**)
  - c. Axiom Worldwide, LLC is no longer active (it was dissolved on 06/24/2010) (**Attachment 6**)
- #2** 4. Our search of 510(k) submissions did not show any 510(k)s associated with Excite Medical Corp or HTRD Group Hong Kong, Ltd. for the DRX5000 and DRX9000 devices assembled by Excite Medical.
5. [REDACTED]
6. [REDACTED]
7. Our search of the two 510(k)s, K023160 and K060735 showed that in 2002, Axiom Worldwide, Inc. (listed by FDA as Axiom USA, Inc.) submitted these 510(k)s:
  - a. K023160 - DRX5000 Lumbar and Cervical Decompression System (**Attachment 7**)
  - b. K060735 - DRX9000 Lumbar Decompression System (**Attachments 8 and 10**)

[REDACTED]

Mr. Musallam stated that in 2011 Excite Medical had (b) (4) in revenue. He added that (b) (4) of Excite Medical's revenue generated stemmed from servicing older devices made by Axiom, (b) (4) from selling used devices, and (b) (4) from new devices assembled by the firm.

## **PRESS RELEASE: DRX9000™ NOW EXCLUSIVELY AVAILABLE THROUGH EXCITE MEDICAL**

**CONTACT: Livia Fernandes**  
**Excite Medical Corp.**  
**Phone Number: 813-210-1000**  
**FOR IMMEDIATE RELEASE - Tampa, FL March 31, 2011:**

In response to a large number of inquiries for an explanation of what happened to Axiom Worldwide™ and who can manufacture, sell and service the DRX9000™, Excite Medical would like to provide the public with the following timeline of the events of the past year:

**March 2010** – Axiom Worldwide™ closes its doors and assigns all of its physical and intellectual property rights to Progress Bank through court proceedings.

**July 2010** – HTRD Limited Honk Kong purchases all of Axiom Worldwide’s physical and intellectual property from Progress Bank free of any liabilities.

**August 2010** – HTRD chooses Excite Medical Corp based in Tampa, Florida as their exclusive contract manufacturer and distributor of DRX9000™, DRX9000C™, DRX9500™ and all devices previously manufactured by Axiom Worldwide™.

**December 2010** – The United States Patent and Trademarks office transfers the legal ownership of all trademarks previously owned by Axiom Worldwide™ to HTRD Limited. A few of these trademarks include:

“Axiom Worldwide” (Serial No 76533071)  
“DRX 9000 (Serial No. 76533070)

**#3 December 2010** – The United States Food and Drug Administration(FDA) transferred the legal ownership of the following 510(k)s:

Device Name	510 (k) Number
DRX2000	K010292
DRX3000	K022602
DRX5000	K023160
DRX9000	K060735

**January 2011** – Excite Medical becomes registered with the FDA as the new contract manufacturer of the DRX9000™ and the DRX5000™ (DRX9000C™). Also, Excite Medical proudly to announces the achievement of becoming ISO 13485 Certified.

**March 2011** – HTRD enters into an exclusive agreement with Danaher for purchasing the servo amplifier and motor for the DRX9000™. This strategic alliance ensures that HTRD™ and Excite Medical will have the exclusive capability of building and supporting DRX9000™ systems.

### **ABOUT HTRD AND EXCITE MEDICAL CORP.**

HTRD Group Hong Kong Limited is the current owner of Axiom Worldwide’s intellectual property rights, including the DRX9000™ and related devices. These devices were previously produced by Axiom Worldwide™, but have been sold by its bank under legal proceedings. HTRD has chosen Excite Medical Corp., for its knowledge and ability to distribute & support these devices successfully, to be the exclusive contract manufacturer and distributor worldwide.

If you have any questions to the above mentioned information and would like supporting documentation of any portion please feel free to contact Excite Medical at 001-813-210-1000.