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News Update

TUV Rheinland Confirms Apparent Fraud in Mislabeling of DRX Products Manufactured by HTRD and Excite Medical

Tampa, Florida, USA - August 28, 2012. In the ongoing efforts to protect its Intellectual Property associated with the DRX family of products, Axiom Worldwide has received verification that HTRD and Excite Medical continue to mislead the international medical community. In this specific case it is through false and fraudulent usage of CE Mark labeling.

The CE Mark is the standard of safety, testing and validation that is applied to a product, in this case a medical device, and certifies that a manufacturer has passed the rigorous inspections required by law. When a buyer purchases a machine that has a CE Mark affixed to the medical device, they presume that the device is safe, has passed all of the independent laboratory testing and that their manufacturing process has been thoroughly inspected. While the investigation is still underway and rapidly expanding across the European Union with other agencies, photographic evidence has been submitted to authorities to authenticate the fraud. What is known is that Excite Medical and HTRD have sold and installed machines that list TUV Rheinland LGA Products GmbH as having provided the necessary CE Mark certificates. However, according to a letter addressed to Axiom Worldwide directly from TUV Rheinland LGA Products GmbH on August 22, 2012, *"According to our database enquiry we did neither issued [sic] certificates for Excite Medical Corp nor for HRDT [sic] Group Hong Kong Limited which would entitle the aforementioned companies to use the CE marking in combination with TUV Rheinland notified body number 0197."* A copy of the letter received by TUV Rheinland can be viewed at www.AxiomWorldwide.com.

The TUV Mark CE is what is considered a "gold standard" label reflecting a mark of safety achieved through testing, risk assessments, and a measurable quality management system. The quality management assessment, ISO:13485, includes examination of the manufacturer's technical documentation, including a valid US FDA 510(k) clearance, all of which must be reviewed prior to issuance of the CE mark certificates. CE Marking on a product can only be granted by a notified body, such as TUV, and is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. Notified bodies are private organizations or government agencies that can serve as independent test laboratories and perform the steps identified in the relevant Medical Device Directives.

HTRD is a Chinese based company that represents to the public that it manufactures out of Hong Kong, while Excite Medical is a USA based company. It is a violation of federal law for a US company to place unauthorized medical devices on the market for purposes of interstate commerce in the USA. The recent discovery has been reported to the appropriate federal agencies and certifying bodies responsible for overseeing the proper labeling of medical devices. As the original developers and manufacturers of the DRX family of products, including the DRX9000 and DRX 9000C, Axiom fully intends to assist in the investigation as requested.

Mr. James Gibson is the sole founder of Axiom Worldwide, Inc and continues to serve as its President and CEO. Axiom Worldwide was created in 2000 in Tampa, Florida and obtained multiple US FDA 510(k) clearances over the years. Axiom Worldwide invented its flagship products, the DRX9000 True Non-surgical Spinal Decompression System and the DRX9000C, for use in medical markets around the globe. For more information please visit the Axiom Worldwide website at www.AxiomWorldwide.com or for more information on the 510(k)s or related court proceedings, contact Mr. James Gibson directly at President@AxiomWorldwide.com.

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Cologne,, 22 August 2012

Request for status of certificates

Dear Mr. Gibson,

Reference is made to your email dated August 20 and 21, 2012 and to the email sent by [redacted] of Integrity Life Scienes, dated August16, 21 and 22, 2012.

[redacted] kindly sent us two photographs which showed rating labels. One rating label mentioned as contract manufacturer the company Excite Medical Corp. and as manufacturer a company called HTRD Group Hong Kong Limited.

According to our database enquiry we did neither issued certificates for Excite Medical Corp nor for HRDT Group Hong Kong Limited which would entitle the aforementioned companies to use the CE marking in combination with TÜV Rheinland notified body number 0197.

Best regards,

i. V. Frank Althoff
(Manager Trade Mark Surveillance)

i. A. Katharina Seidel
(Trade Mark Surveillance)

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