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News Update

HTRD and Excite Medical's CE Marking Agency being investigated for Fraud and "Unscrupulous" Activities

December 21, 2012, Tampa, Florida, USA: While investigating the ongoing fraud being perpetrated against Axiom Worldwide, Inc. by HTRD and Excite Medical relating to Axiom's Intellectual Property, Axiom has been made aware of an intensive and ongoing investigation in the European Union (EU) against HTRD/Excite's notified body, the Czech Republic-based Institute for Testing and Certification (ITC). Since August 2012 when Axiom was made aware of illegally manufactured and fraudulently labeled DRX9000 systems imported into the EU, Axiom has been cooperating with EU authorities in locating other illegal medical devices.

In the EU, the task of determining whether a medical device is safe is the responsibility of private firms called "notified bodies". These notified bodies report directly to the EU authorities and certify that equipment may be legally imported. In ITC's case, investigators have video evidence of a Seoul, Korea company claiming that, *"As part of their relationship with the regulator they did 'all the results' for Asian companies that applied for the necessary CE certification."*

HTRD manufactures adulterated equipment in China and uses its agents such as Excite Medical for international distribution while claiming the machines are "Made In The USA". The illegal equipment is in turn passed on to other companies who may or may not knowingly import the illegal medical devices from Excite Medical.

Other European ministry of health agencies have begun to issue statements to include the Danish Health and Medicines authority issues the following statement, *"The Danish Health and Medicines Authority currently urges caution in relation to using products that have been certified by either of the two notified bodies. The products will be indicated with either the number "1293" or "1023" by the CE mark."*

The investigation was initially started by a team of investigative journalists including the prestigious British Medical Journal posing as representatives of a Chinese company who contacted several regulatory organizations - known as notified bodies - about approving a medical

device for the European market. In a secret video recording obtained by the UK's *The Daily Telegraph*, an ITC representative is shown telling the undercover reporters that *"we are on the side of the manufacturer and their products, not on the side of patients."* Further, an ITC representative promised not to put "obstacles" in the way of approving a hip implant, which had similar design specifications to a banned product suspected of poisoning thousands of patients.

The CE Mark is the standard of safety, testing and validation that is applied to a product and certifies that a manufacturer has passed the rigorous inspections required by law. International customers and governmental agencies rely on the CE Mark when evaluating manufacturers and products – and especially when considering the safety and efficacy of medical devices that are used to treat patients. ITC said it *"categorically refuses The Daily Telegraph's accusation of dishonest practice in conformity assessment of medical devices."* According to Axiom's President, James Gibson, "*To question the conduct of the notified body is, in essence, to call into question all the certifications issued by that organization*."

Gibson added, *"While* The Daily Telegraph's *investigation is not directly related to Non-Surgical Spinal Decompression Equipment, the DRX9000, or DRX family of products, it absolutely publicly calls into question the integrity and diligence of the notified body. Selecting a qualified notified body is both a critical and arduous process, and not one that a manufacturer should conduct haphazardly, especially when the safety of patients is at risk."*

Axiom Worldwide, Inc. is currently litigating against HTRD, Excite Medical, Saleem Musallem, Ilya Marder of El Tech in Russia and others in US Federal Court to protect its Intellectual Property and to stop the defendants from misleading the international medical community relating to the manufacturing and sale of Non-Surgical Spinal Decompression Systems.

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 products, 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.

Please go to the Axiom Worldwide website for more news updates: www.AxiomWorldwide.com and click on the News Link.

Additional International News Links:

BRITISH MEDICAL JOURNAL

1. Joint BMJ / Telegraph investigation exposes flaws in regulation of medical devices

http://group.bmj.com/group/media/latest-news/joint-bmj-telegraph-investigation-exposes-flaws-in-regulation-of-medical-devices

DANISH HEALTH AND MEDICINES AUTHORITY

2. Criticism of CE marking of medical devices in Czech Republic and Slovakia

http://medicaldevices.dk/en/service-menu/news/criticism-of-ce-marking-of-medical-devic--d-slovakia

DRUG WATCH

3. Investigation: European Regulators Considered Licensing Faulty Hip Implant

http://www.drugwatch.com/2012/10/24/investigation-european-regulators-considered-licensing-faulty-hip-implant/

THE TELEGRAPH

4. Faulty medical implants investigation: Patients' health put at risk by unscrupulous EU regulators

http://www.telegraph.co.uk/health/healthnews/9626756/Faulty-medical-implants-investigation-Patients-health-put-at-risk-by-unscrupulous-EU-regulators.html

5. Faulty medical implants investigation: 'We're paid by manufacturer so want deal to succeed'

http://www.telegraph.co.uk/health/healthnews/9632006/Faulty-medical-implants-investigation-Were-paid-by-manufacturer-so-want-deal-to-succeed.html

6. Accusations of 'unscrupulous' EU medical industry hit ČR

http://www.praguepost.com/news/14653-accusations-of-unscrupulous-eu-medical-industry-hit-cr.html