FDA: Do Not Use ShoulderFlex Massagers

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SILVER SPRING, Md., Dec. 21, 2011 /PRNewswire-USNewswire/ -- The U.S. Food and Drug Administration is warning consumers again not to use the Shoulder*Flex* Massager, imported by King International and sold by various companies, due to serious potential health risks.

(Logo: http://photos.prnewswire.com/prnh/20090824/FDALOGO)

The Shoulder*Flex* Massager is a personal massage device sold in retail stores, catalogs and over the Internet. It is intended to provide users with a deep tissue massage to the neck, shoulders and back area while lying down.

Hair, clothing or jewelry can become entangled in the Shoulder*Flex* Massager and cause serious injury or even death from strangulation. There have been reports of one death and one near death, due to strangulation, associated with the use of this device.

"The Shoulder*Flex* Massager poses serious risks. Consumers should stop using this device, health care providers should not recommend it to their patients and businesses should stop distributing and selling the device," said Steve Silverman, director of the Office of Compliance in the FDA's Center for Devices and Radiological Health.

King International recalled the Shoulder*Flex* Massager on Aug. 31, 2011; however, during a recent compliance audit, the FDA found that the company has gone out of business. King International has not followed through with recall procedures; the 800 number established by the firm for this recall is no longer in service; and many of the companies that sell this device are not aware of the recall or did not properly notify customers who purchased the massager.

Because of this failure, the FDA is concerned that consumers may not be aware of the risks posed by the Shoulder*Flex* Massager and may still be using this dangerous product.

The FDA recommends that customers and consignees safely dispose of the Shoulder*Flex* Massagers so that the device
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SOURCE [1]

Links:
[1] http://www.bio-medicine.org/medicine-technology-1/FDA-3A-Do-Not-Use-ShoulderFlex-Massagers-23086-1/