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LHASA MEDICAL, INC.

K962916

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SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS

In general, acupuncture needles have been used in the practice of acupuncture in the United States for now over 30+ years. Since this time, we are not aware of any serious or life threatening accidents involving acupuncture needles.

The acupuncture needles which were in commercial interstate distribution prior to May 28, 1976 were sold as a non-sterile, reusable acupuncture needle.

However, the acupuncture needles which are now sold in 1996 offer greater safety since they are a sterile, single use only acupuncture needle.

The subject of this 510k application - the Hua-Xia acupuncture needle - is a sterile, single use only acupuncture needle. The Hua-Xia acupuncture needle meets the general specifications and parameters for an acupuncture needle and is effective for the practice of acupuncture.

Lhasa Medical has been selling the Hua-Xia brand acupuncture needle since 1990 as an "Investigational device, limited by U.S. law to investigational use". Since 1990, Lhasa Medical has not received any serious claims of injuries caused by the Hua-Xia acupuncture needle.

Additional information on the safety and effectiveness of the Hua-Xia acupuncture needle will be made available if it is requested.

In conclusion, based on the information provided with this 510k application, the Hua-Xia acupuncture needle meets the criteria for 510k acceptance. The Hua-Xia needle is equivalent to acupuncture needles which were in commercial distribution prior to May 28, 1976. Also, the Hua-Xia needle is equivalent to other acupuncture needles which are now being sold through interstate commerce.

← Not Accepted