LHASA MEDICAL, INC.

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November 8, 1996

JAN 30 1997

PRE-MARKET NOTIFICATION
510(k) SUMMARY
(As Required by 21 CFR 807.93)

Acupuncture needles are defined as devices intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.
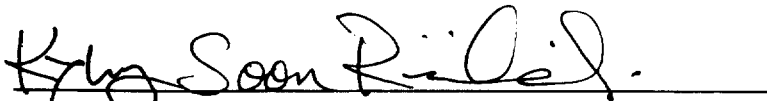
Acupuncture needles have been used for the general practice of acupuncture in the United States for over 30 years. Since this time, we are not aware of any serious or life threatening accidents involving acupuncture needles.

Acupuncture needles which were sold through commercial interstate distribution prior to May 28, 1976 were non-sterile, reusable acupuncture needles. Acupuncture needles which are currently being marketed through interstate distribution (ie, 1996) offer greater safety since they are sterile, single use only acupuncture needles.

The subject of this 510(k) application - the CW acupuncture needle - is a sterile, single use only acupuncture needle. The CW acupuncture needle meets the general specifications and criteria for an acupuncture needle and is effective for the practice of acupuncture.

The CW brand acupuncture needle is manufactured in Korea and has been imported and sold through interstate commerce in the USA since 1986 under the FDA labeling restrictions of: "Caution: Investigational device limited by U.S. law to investigational use". Since 1986, no accidents or device failure claims have been reported as a result of using the CW brand acupuncture needle.

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

Kyung Soon Riihimaki, President

11-8-96

Date

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Premarket Notification (510(k) Number):