

EXHIBIT 2

5 1998

Lorac, Inc.
134 North Washington
Naperville, IL 60540
Tel 1+630-548-4456
Fax 1+630-548-4457
Contact: Sandra Sobczak, President
November 26, 1997

510(k) Summary of Safety and Effectiveness as required by 21 CFR 807.93

1. **Identification of the Device:**
 Proprietary-Trade Name: **Singer Acupuncture Needles, Single Use, Sterile.**
 Classification Name: **NEEDLE, ACUPUNCTURE, SINGLE USE**
 Common/Usual Name: **ACUPUNCTURE NEEDLE, SINGLE USE**
2. **Equivalent legally marketed devices:** These products are similar in design and function to: **Seirin Acupuncture needles, K962809 and Lhasa Acupuncture needles, K962916.**
3. **Indications for Use (intended use):** **To pierce the skin the practice of acupuncture by qualified practitioners as determined by the states.**
4. **Description of the Device:** **The needles are sterile, for single use only. They have a stainless steel shaft and a polystyrol handle. The handles are color coded for size.**
5. **Safety and Effectiveness, comparison to predicate device.** **The results of bench and user testing indicates that the new devices are as safe and effective as the predicate devices. Materials used in their manufacture are the same as used by predicate devices. The needles are equivalent to those which were in distribution in the United States prior to 1976, but are now sterile and for single use only. In the 30+ years that acupuncture needles have been in use in the United States, we are not aware of any serious or life-threatening accidents involving acupuncture needles.**



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 1998

Ms. Sandra Sobczak
President
Lorac, Incorporated
134 North Washington Street
Naperville, Illinois 60540

Re: K974616
Trade Name: Singer Acupuncture Needles
Regulatory Class: II
Product Code: MQX
Dated: December 5, 1997
Received: December 11, 1997

Dear Ms. Sobczak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

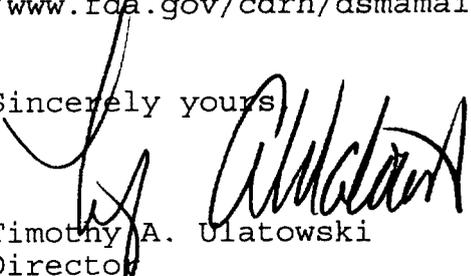
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K974616

i) Indications for Use

510(k) Number K974616

Device Name: Singer Acupuncture Needles (single use, sterile)

Indications for Use:

To pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Brenda Golde*
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number _____

Prescription Use OR Over the Counter Use _____
(Per 21 CFR 801.109)