

K991958

AUG 13 1999

**510 (k) NOTIFICATION
KIEL LABORATORIES, INC.
SUMMARY**

**KIEL LABORATORIES, INC.
2225 CENTENNIAL DRIVE
GAINESVILLE, GA. 30504**

**CONTACT: TANYJA PORCHÁ
PHONE: (770) 534-0079
FAX: (770) 534-0229**

DATE PREPARED: 6/04/99

| | |
|----------------------|---|
| DEVICE NAME: | LICE COMB AND PRETREATMENT KIT |
| PROPRIETARY NAME: | KLOUT™ LICE COMB and PRETREATMENT SHAMPOO |
| CLASS: | I |
| PANEL: | GENERAL HOSPITAL |
| PRODUCT CODE: | LJL |
| CLASSIFICATION NAME: | DETECTORS AND REMOVERS, LICE (including combs) |
| PREDICATE DEVICE: | CLEAR™ LICE EGG REMOVER SYSTEM - K981147 LICEMEISTER™ COMB - K981250 |

DESCRIPTION AND INTENDED USE:

The kit consists of two components, the comb and the combing pretreatment shampoo. The comb is stainless steel with the teeth set to 0.3 mm (300 micron) spacing and capable of removing nits which are greater than 0.3 mm when attached to the hair. The second element is a shampoo that contains no pesticides but does facilitate lice removal and allows for rinsing and combing the nits out of the hair.

intended use/indications: the removal of head lice and their eggs (nits) from hair

BASIS FOR COMPARISON:

| basis for comparison | KLOUT™ kit | CLEAR® system |
|------------------------|------------|---------------|
| comb included | yes | yes |
| removal of nits | yes | yes |
| ovicidal | no | no |
| removal of lice | yes | no |
| pediculicidal | no | no |
| where used | home | home |
| active ingredient | none | none |
| anatomical site of use | hair/head | hair/head |



AUG 13 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Tanya Porcha
Director of Regulatory Affairs
Kiel Laboratories, Incorporated
2225 Centennial Drive
Gainesville. Georgia 30504

Re: K991958
Trade Name: Klout Shampoo and Lice Combing Pretreatment Kit
Regulatory Class: I
Product Code: LJL
Dated: June 09, 1999
Received: July 30, 1999

Dear Ms. Porcha

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.

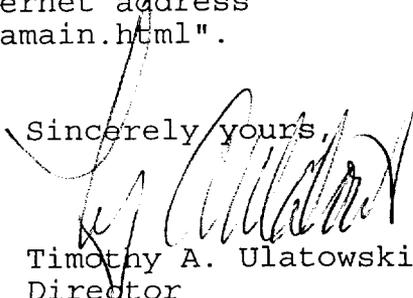
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

Page 2 - Mr. Porcha

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) 594-4692. 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

K991958

510 (k) NOTIFICATION
KIEL LABORATORIES, INC.

intended use/indications: the removal of head lice and their eggs (nits) from hair

Prescription Use _____
(Per 21 CFR 801.109)

Over-the-Counter Use _____ ✓

Over-the-Counter

Steven Bolden

Sign-Off

K991958