

K 981037

EXHIBIT 5
(05/18/98)

510(k) Summary

Submitted by: Daniel J. Manelli
Farkas & Manelli, P.L.L.C.
2000 M Street, NW (Suite 700)
Washington, DC 20036
Telephone: 202-261-1000

On behalf of Care Technologies, Inc.
510(k) Submission: Clear™ Special Nit Comb

Date Summary Prepared: May 18, 1998

Name of device: Clear™ Special Nit Comb

Predicate Devices: Innocomb Lice Comb
Innomed PD-1 Kit

Description of Device:

The product is a nit comb intended for use in detecting and removing lice eggs from the hair. It is constructed of closely spaced stainless steel teeth imbedded in a high density polyethylene handle. The points and edges of the teeth are rounded so as not to cut or damage hair or scalp. The comb can be cleaned with soap and water after use and can withstand boiling water disinfection. The product is substantially equivalent to other nit removal combs, including the Innocomb Lice Comb (K822421) and Innomed PD-1 Kit (K822574).

The technological characteristics of the Clear Special Nit Comb are the same as other marketed nit combs, including the predicate devices, which range from 100 to 200 microns of spacing between comb teeth. The minimum width of a lice nit adhering to a human hair is approximately 300 microns (0.3mm). The spacing between the teeth of the Clear Special Nit Comb is 200 microns (0.2mm).

Intended use: Lice egg detection and removal.



MAY 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Care Technologies, Incorporated
C/O Mr. Daniel J. Manelli
Farkas & Manelli, P.L.L.C.
2000 M Street, NW (Suite 700)
Washington, DC 20036

Re: K981037
Trade Name: Clear™ Special Nit Comb
Regulatory Class: Unclassified
Product Code: LJJL
Dated: March 18, 1998
Received: March 19, 1998

Dear Mr. Manelli:

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 legally marketed predicate 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 (Premarket 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 requirements, 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

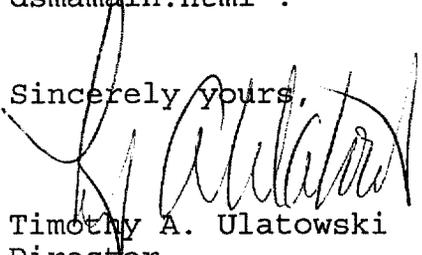
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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" (21CFR 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/dsma/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

510(k) Number (if known): K981037

Device Name: Clear (tm) Special Nit Comb

Indications For Use:

For lice egg detection and removal

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Curienti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K981037

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)