

K974190

I. 510(k) AMENDMENT SUMMARY

NOV 19 1997

Submitted by: Consolidated Products and Services
100-L Messina Drive
Braintree, MA 02184

Contact: Wayne Kritzman

Date: October 31, 1997

Proprietary Name: Instant Cold Pack Limb Kit Transporter

Classification Name: Hot/ Cold Disposable Pack (21CFR 890.5710)

Predicate Device: Disposable Instant Cold Pack
(current 510(k) K890553 to be amended).

Description: The CP&S Disposable Instant Ice Pack Limb Kit Transporter is an instant ice pack with an added pouch for the insertion of a severed body part for transport to the hospital emergency room or replantation surgery.

The Instant Cold Pack Limb Kit Transporter is activated in the same manner as the Disposable Instant Cold Pack and provides cooling for the severed limb within the gauze lined zip lock top bag. A cool environment above freezing is maintained for approximately 30 minutes.
(Attachment C)

The additional pouch does not affect the safety or efficacy of the disposable Instant Cold Pack.

CP&S feels the Instant Cold Pack Limb Kit Transporter is a tremendous improvement over current practice of placing severed limbs in any available container and placing on ice.

21CFR 890.5710 identifies a disposable cold pack as a "device intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that upon activation, provides cold therapy for body surfaces." The CP&S Instant Cold Pack Limb Kit Transporter compares exactly to this identification.

Also attached are studies showing that the severed limb should be stored at above freezing temperatures and that proper techniques for preservation of the amputated part are important for survival.

(Attachment D).

The above information supports CP&S' request that the Instant Cold Pack Limb Kit Transporter be added to the 510(k) for Disposable Instant Cold Pack.

Intended Use:

The CP&S Disposable Ice Pack Limb Kit Transporter provides an environment above freezing for a severed body part while being transported to the hospital emergency room or replantation surgery.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Wayne Kritzman
Manufacturing Manager
Consolidated Products and Services, Inc.
100-L Messina Drive
Braintree, Massachusetts 02184

NOV 19 1997

Re: K974190
CP&S Disposable Instant Cold Pack
Limb Kit Transporter
Regulatory Class: I
Product Code: IMD
Dated: October 31, 1997
Received: November 4, 1997

Dear Mr. Kritzman:

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.

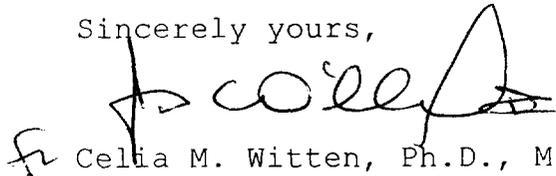
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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. Wayne Kritzman

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) 594-4659. 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,

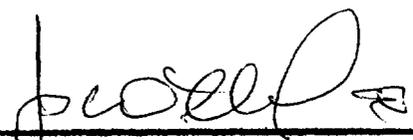
 fr
Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use:

The CP&S Disposable Ice Pack Limb Kit Transporter provides an environment above freezing for a severed body part while being transported to the hospital emergency room or replantation surgery.

Over-the-Counter Use X



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 12974190