JUN 2 5 2004

510K SUMMARY FOR

ELASTIC SKIN LIQUID BANDAGE

Number K032948

1.Manufacturer and Applicant- Medpak LLC, 568 Parkside Court
Allentown, PA18104
Contact Person-Joseph G Sant'Angelo, Phone-484-225-5799; 610-530-0530
E-mail-MJMJJS97 @AOL.COM
Date-June 4, 2004

2. **Device Name**
Proprietary Name: Elastic Skin Liquid Bandage
Common Name: Liquid Bandage
Classification Information:

Class-1

Name	Product Code	21 CFR Ref.	Panel
Liquid Bandage	KMF	880.5090	General & Plastic Surgery

3.**Predicate Device**
CURAD ® Spray Bandage, 510(k) No. K022645

4. **Device Description**
Elastic Skin is a liquid solution film-forming product. The product solution is packaged in a container with a brush applicator. A thin coating of solution is applied on the wound with the applicator forming a protective clear film in less than one minute. Additional coats may be applied if needed. The film may be removed by peeling away from the skin with the use of mild soap and water.

Elastic Skin Liquid Bandage composition is as follows:

The main component of Elastic Skin is an organic polymer dissolved in an organic solvent.

5. **Intended Use**
Elastic Skin Liquid Bandage provides a covering over minor cuts and scrapes that are dry and clean.

6. Substantial Equivalence and Technical Information

The intended use of Elastic Skin Liquid Bandage and CURAD® are the same. Both products use a film forming liquid polymer solution to cover minor wounds on the skin, which forms a clear film on the skin when the solvent evaporates. Both products have many of the same functional characteristics such as helping to protect the minor wounds from germs, while providing flexibility and water vapor permeability.

7. Performance Testing

The following laboratory tests where conducted to establish the safety of Elastic Skin Liquid Bandage:

Self Preservation Study-Microorganisms listed in USP<51>
Sterility-Mold and Fungus by Agar Plate Count and Identification PRJ
Primary Skin Irritation-Rabbits
Bacterial Mutagenicity Test-Ames Assay
Repeated Patch Dermal Sensitization -Buehler Method. Guinea Pigs
ISO Agarose Overlay Using L-929 Mouse Fibroblast Cells (Cytotoxicity Test)
Microbial Film Barrier- Psuedomonas Aeruginosa ATCC 9027

All tests gave satisfactory results, indicating that Elastic Skin Liquid Bandage is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2004

Mr. Joseph G. Sant'Angelo
President
Medpak, LLC
568 Parkside Court
Allentown, Pennsylvania 18104

Re: K032948
Trade/Device Name: Elastic Skin Liquid Bandage
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: May 5, 2004
Received: May 6, 2004

Dear Mr. Sant'Angelo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

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

Enclosure

510(k) Number (if known): K032948

Device Name: Elastic Skin Liquid Bandage

Indications for Use:

Elastic Skin Liquid Bandage is indicated for providing a covering over minor wounds and scrapes that are clean and dry.

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032948

(Optional Format 1-2-