K034574

510(k) SUMMARY

AUG 21 2003

The Summary of Safety and Effectiveness on the GluSeal™ reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant:	Don Blacklock GluStitch, Inc. 7188 Progress Way, #307 Delta, BC., V4G 1M6
Telephone:	(800) 667-2130
Facsimile:	(877) 450-4000
Date:	June 10, 2003
Name:	GluSeal™
Classification:	Liquid Adhesive Bandage, 21 CFR 880.5090
Predicate:	CLOSURE Medical Corporation's LIQUIDERM™ Liquid Adhesive Bandage, K002338 – market clearance date, January 29, 2001.
Description:	GluSeal™ is monomeric 2 octyl cyanoacrylate. This compound, which exists in monomeric form in the plastic containers, polymerizes extremely rapidly in the presence of anions, especially of hydroxyl ions (in the presence of water). GluSeal™ will be packaged in three different ways ranging from a multiuse bottle containing 5 ml cyanoacrylate; a multiuse vial containing 1 ml cyanoacrylate, and a kit containing 12 x 0.2 ml disposable applicators. Each of the multiuse kits will contain application pipettes and administration dishes or administration trays.
Intended Use:	GluSeal™ liquid adhesive bandage is intended to cover minor cuts, scrapes, burns, and minor irritations of the skin and help protect them from infection.
Warnings:	• Do not apply GluSeal™ adhesive to the eye(s). If contact with the eye(s) occurs, keep the eye(s) closed and covered, and immediately contact an ophthalmologist. No attempt should be made to open the eye(s). The adhesive will lose its adhesion over time, between one and three days, and the eye(s) will open spontaneously with no damage. • Do not use on infected areas, or wounds that are draining.
Cautions:	• Do not use on mucosal surfaces (e.g., oral cavity, lips). • Do not use if hypersensitive to cyanoacrylate.
Intended Use and Chemical Characteristic:	The intended use and chemical structure of the GluStitch, Inc.'s GluSeal™ and CLOSURE Medical Corporation's LIQUIDDERM™ are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2003

Mr. Don Blacklock
President
GluStitch, Inc.
7188 Progress Way, #307
Delta, British Columbia
V4G 1M6 Canada

Re: K030574
Trade/Device Name: GluSeal™
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: June 10, 2003
Received: June 11, 2003

Dear Mr. Blacklock:

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,

for Mark N Melkerson

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): K030574

Device Name: GluSeal™

Indications For Use:

GluSeal™ liquid adhesive bandage is intended to cover minor cuts, scrapes, burns, and minor irritations of the skin and help protect them from infection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

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

510(k) Number K030574

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

(Optional Format 1-2-96)