JUN 2 0 2002

SHOFU DENTAL CORPORATION
1225 Stone Drive, San Marcos, California 92069-4059 U.S.A.
Tel.: (760) 736-3277 • FAX.: (760) 736-3276

K021613

510(k) SUMMARY

Submitted by:	Robert Noble, President Shofu Dental Corporation 1225 Stone Drive San Marcos, CA 92069-4059 (760) 736-3277 FAX: (760) 736-3276
Company Contact:	Robert Noble, President
Date Summary Prepared	May 14, 2002
Trade Name	Niveous Liquid Dam
Common Name	Resin dam
Classification	EIE
Product Code	872.6300
Substantially Equivalent Devices	FastDam [510(k) Number – K972775] OpalDam [510(k) Number – K971284]

Description of Niveous Liquid Dam

Niveous Liquid Dam is a light-cured resin used for soft tissue isolation/protection during teeth whitening procedures. The material is dispensed from a syringe into the gingival crest just shy of the tooth structure. The resin is light-cured (polymerized) on the soft tissue by exposure for 20 seconds per section of material.

Intended Use:

The Niveous Liquid Dam resin is indicated to protect soft tissue during in-office bleaching.

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Kit Components:

Niveous Liquid Dam is a component in the Niveous Professional Tooth Whitening System. The kit consists of the following components:

1. Syringe containing Niveous Liquid Dam
2. Bleach Gel Droplet
3. Booster Brush
4. Dappen Dish

Biocompatibility

Niveous Liquid Dam is similar in use and formulation to other dental dams that have been on the market for several years. (Interdent Incorporated, FastDam 510(k) K972775, among others) The formulation does not contain any new or non-conventional chemicals; therefore, new biocompatibility testing is unwarranted.

Nonclinical tests that support a determination of substantial equivalence

The chemical composition is comparable to FastDam, 510(k) K972775, and has the same physical and chemical characteristics.

Conclusion

The Niveous Liquid Dam is substantially equivalent to other liquid dam resins such as FastDam 510(k) K972775 and OpalDam 510(k) K971284.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2002

Mr. Robert Noble
President
Shofu Dental Corporation
1225 Stone Drive
San Marcos, California 92069-4059

Re: K021613
Trade/Device Name: Niveous Liquid Dam
Regulation Number: 872.6300
Regulation Name: Rubber Dam and Accessories
Regulatory Class: I
Product Code: EIE
Dated: May 14, 2002
Received: May 16, 2002

Dear Mr. Noble:

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 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. However, you are responsible for determining that the medical devices you use as components of the Niveous kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the Act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

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 the labeling regulation (21 CFR Part 801 and additionally Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K021613

Device Name:

Niveous Liquid Dam

Indications For Use:

The Niveous Liquid Dam resin is indicated to protect soft tissue during in-office bleaching.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021613

(Optional Format (3-10-98)