K014088

JUN 7 2002

510(k) SUMMARY

Date Prepared	30 November 2001
510(k) No.	
Submitter	Baxter Healthcare Corporation Baxter BioScience 550 North Brand Boulevard Glendale, CA 91203
Contact	Arlene Vidor Vice President, Regulatory Affairs, North America
Device Name	DUPLOREACH Extended Applicator
Common/Usual/ Classification Name	Syringe, Piston
Predicate Device	SEALOUETTE Fibrin Sealant Applicator 510(k) No. K992351 Baxter Healthcare Corporation, Baxter BioScience
Device Description	The DUPLOREACH Extended Applicator, which consists of a stainless steel encased dual-lumen cannula that attaches to the DUPLOJECT Double-Barreled Syringe Applicator device via two screw-on leur style connectors, is used for the delivery of TISSEEL Fibrin Sealant in hard to reach locations. The Extended Applicator is equipped with a replaceable tip that is attached via a sliding lock mechanism, ensuring the tip does not detach during use. A trigger mechanism on the body of the device locks and unlocks the tip. A window above the trigger provides the user with a clear indication when the tip is in the fully locked position. Two replacement spray tips are supplied with each Extended Applicator device. The primary changes from the predicate device are the adaptations necessary to allow the DUPLOREACH Extended Applicator to be used with the DUPLOJECT applicator device and the extension of the dual-lumen cannula before the mixing chamber. Other minor modifications were made to either support these primary changes or to enhance the functionality of the device. No modifications were made to the DUPLOJECT device to accommodate the DUPLOREACH Extended Applicator. The modified device has been shown to be substantially equivalent to the predicate device through *in vitro* testing, in which the mixing of TISSEEL Fibrin Sealant was shown to be equivalent in both the cleared and modified devices.
Intended Use	The DUPLOREACH Extended Applicator, in conjunction with the DUPLOJECT Double-Barreled Syringe Applicator Device, is intended for the mixing and delivery of TISSEEL VH Fibrin Sealant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 2002

Ms. Arlene Vidor
Vice President, Regulatory Affairs
Baxter Healthcare Corporation
Baxter Bioscience Division
550 North Brand Boulevard
Glendale, California 91203-1900

Re: K014088
Trade/Device Name: DUPLOREACH Extended Applicator
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: April 25, 2002
Received: April 26, 2002

Dear Ms. Vidor:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . 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 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,

Susan Runner

for 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 STATEMENT

510(k) Number	K014088
Device Name	DUPLOREACH Extended Applicator
Indications for Use	The DUPLOREACH Extended Applicator, in conjunction with the DUPLOJECT Double-Barreled Syringe Applicator Device, is intended for the mixing and delivery of TISSEEL VH Fibrin Sealant.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014088