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K981089

Summary of Safety and Effectiveness for the Tissomat® and Spray Set

Submitter

Baxter Healthcare Corporation
Hyland Immuno
550 North Brand Boulevard
Glendale, California 91203-1900

Date Summary was Prepared

03-May-2000

Name(s) of the Device

Tissomat® and Spray Set

Identification of Predicate Device(s)

Duploject®
Baxter Healthcare Corporation, Hyland Immuno
K973510

Description of the Device

The Spray Set is a sterile, pyrogen-free, single-use device indicated for use in the simultaneous application (by spraying) of the two components of Tisseel® Fibrin Sealant onto wound surfaces. It consists of a Spray Head and connection tube with sterile filter. The Spray Set is attached to the Duploject® two-syringe holder, a device that has already been cleared by the FDA through Premarket Notification [510(k)]. The connection tube connects the Spray Head to the Tissomat® device, a propellant gas control device.

The Tissomat® device controls and releases propellant gas provided by a propellant gas source (compressed air or nitrogen). The Tissomat® device is indicated for use only with the Spray Set in the simultaneous application (by spraying) of the two components of Tisseel® Fibrin Sealant onto wound surfaces.

The Tissomat® and Spray Set are used for the spraying of wound surfaces, when uniform coverage is essential.

Intended Use

The Tissomat® and Spray Set are intended for use in the simultaneous application (by spraying) of the two components of Tisseel® Fibrin Sealant onto wound surfaces. The Spray Set is attached to the Duploject® two-syringe holder and is equipped with a Spray Head and a connection tube which connects the Spray Head to the Tissomat® device, a propellant gas control device.

Comparison of Device Characteristics to Predicate

The Tissomat® and Spray Set are two parts forming a functional unit, which is intended to be used in conjunction with the Duploject® two-syringe holder, the predicate device cleared through Premarket Notification [510(k)]. The Spray Set has the same technological characteristics as the Duploject® device. The Tissomat® device controls and releases propellant gas provided by a propellant gas source (compressed air or nitrogen). Use of this pressure regulating technology in this application is supported by performance testing, as described below, and by the fact that this technology has been used in many other surgical applications, e.g., irrigation systems and insufflators.

Performance Testing

A study was conducted to compare the degree of mixing of Tisseel® Fibrin Sealant using the Duploject® two-syringe holder with the Tissomat® and Spray Set, versus using the Duploject® two-syringe holder with an application needle. The results show that at least an equal degree of mixing was reached by using the Tissomat® and Spray Set as with using the application needle.

A study was conducted to compare the hemostatic efficacies of Tisseel® Fibrin Sealant using the Duploject® two-syringe holder with Tissomat® and Spray Set, versus using the Duploject® two-syringe holder with an application needle, in a rabbit liver abrasion model. The results show that the efficacy of Tisseel® Fibrin Sealant is equivalent whether the product is applied by spraying or by using an application needle.

A study was conducted to measure the gas pressure at a (simulated) wound surface using the Duploject® two-syringe holder with the Tissomat® and Spray Set. The results demonstrate a recommended maximum pressure of 2 bars (28.5 psi) for the Tissomat® device and a minimum spraying distance of 10 cm.

The Tissomat® and Spray Set was used clinically to treat a pediatric burn victim on an emergency basis. The Tissomat® and Spray Set were used during multiple operative procedures, in conjunction with the Duploject® two-syringe holder, to deliver fibrin sealant for cultured epidermal autograft adherence and hemostasis. There were no adverse events associated with use of the Tissomat® and Spray Set. Additionally, the surgeon reported this device to be an efficacious method of providing optimal coverage of fibrin sealant to the surgical site.

The Tissomat® and Spray Set have been licensed for many years in Europe, Canada, and other countries, and have been successfully used in more than 250,000 applications of fibrin sealant.

Conclusion

The nonclinical testing along with many years of clinical experience demonstrate that the Tissomat® and Spray Set, used in conjunction with the Duplojject® two-syringe holder (the predicate), is a safe and efficacious method of delivering Tisseel® Fibrin Sealant and performs according to required specifications (e.g., adequate mixing of the solutions, appropriate regulation of pressure).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2000

Ms. Arlene Vidor
Vice President, Regulatory Affairs
North America
Baxter Healthcare Corporation
Hyland Division
550 North Brand Boulevard
Glendale, California 91023

Re: K981089
Trade Name: Tissomat® and Spray Set
Regulatory Class: II
Product Code: FMF
Dated: May 3, 2000
Received: May 4, 2000

Dear Ms. Vidor:

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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 premarket 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.

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) 594-4692. 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,

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

Enclosure

510(k) Number

K981089

Device Name

Tissomat® and Spray Set

Indications for Use

The Tissomat® and Spray Set are intended for use in the simultaneous application (by spraying) of the two components of Tisseel® Fibrin Sealant onto wound surfaces. The Spray Set is attached to the Duploject® two-syringe holder and is equipped with a Spray Head and a connection tube which connects the Spray Head to the Tissomat® device, a propellant gas control device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

☑ Prescription Use (per 21 CFR § 801.109)

☐ Over-the Counter Use

Brenda Bolka

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981089