CoStasis/DynaStat Surgical Hemostat - P990030

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name:	CoStasis/DynaStat Surgical Hemostat
Manufacturer:	Cohesion Technologies, Inc.,
Address:	2500 Faber Place, Palo Alto, CA 94303
Approval Date:	June 13, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p990030a.pdf

What is it? CoStasis/DynaStat is a sprayable liquid used during surgery to control bleeding. The active ingredients, both derived from cows, are connective tissue (collagen) and a clot-promoting material (thrombin). When sprayed onto bleeding tissue, the product forms a gel that adheres to the tissue and retards the bleeding. It is designed to remain intact during the critical wound-healing period and is absorbed by the body over time.

How does it work? The components in CoStasis accelerate the body's clotting mechanism, which serves to produce a physical barrier to blood flow.

When is it used? CoStasis is used in surgical procedures (other than neurological, eye, and urinary tract surgery) to help in the control of bleeding when conventional procedures are ineffective or impractical.

What will it accomplish? CoStasis is sprayed directly onto the bleeding site; it adheres to tissues, and stops bleeding during surgery. It functions without the need for manual pressure or the need to hold the material in place. And, unlike some other methods of controlling bleeding, CoStasis doesn't use ingredients derived from human blood, so there is no contamination risk.

When should it not be used? CoStasis should not be injected into, nor be allowed to enter blood vessels. It should not be used in patients with known allergies to cow-derived materials.

Additional information: The SSED and Labeling will be available at:
http://www.fda.gov/cdrh/pdf/p990030.html

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