Medstone STS™ Lithotripter - P970042

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:	Medstone STS™ Lithotripter
Manufacturer:	Medstone International, Inc.
Address:	100 Columbia, Suite 100, Aliso Viejo, CA 92656
Approval Date:	September 5, 2000
Approval Letter:	http://www.fda.gov/cdrh/pdf/p970042a.pdf

What is it? The device is a shock wave lithotripter. It consists of a patient table, shock wave generator, ultrasound imaging system, and a heart monitor.

How does it work? The Medstone STS™ Lithotripter uses high energy shock waves to fragment gallstones. These shock waves are generated by the deviceand delivered to the patient. Ultrasound is used to locate the gallstone and to monitor fragmentation.

When is it used? This device is used in combination with a drug (Actigall®). The drug is used after the lithotripsy treatment to dissolve any remaining stone fragments. This drug/device treatment is intended for patients for whom conventional surgery would not be advisable, and is used for single gallstones that measure 4-20 mm in size and are composed mainly of cholesterol

What will it accomplish? Approximately half of the patients undergoing this treatment will be free of all gallstone fragments following 2 years of drug therapy. The primary side effects are diarrhea, as well as pain in the gallbladder region.Approximately 10% of patients having the procedure will require surgery to remove their gallbladders due to remaining stone fragments or gallstone symptoms.

When should it not be used?

This treatment should not be used in patients who:

- have blood clotting disorders or are taking blood thinning medication, are pregnant,
- have cardiac arrhythmias (abnormal heart rhythms) or use a pacemaker,
- have a gallstone that cannot be seen with ultrasound or x ray,
- have a non-functioning gallbladder,
- have a calcified gallstone,
- have a bile duct stone,
- have significant liver disease, or

- are unable or unwilling to take Actigall® for the prescribed period of time.

Additional information: Summary of Safety and Effectiveness and labeling are available at: http://www.fda.gov/cdrh/pdf/p970042.html

Discussions of procedure: type “lithotripter” at http://www.ncbi.nlm.nih.gov/entrez/query

(Updated 5/31/2001)