# Hydro ThermAblator® P000040

*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.*

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| Product Name: | Hydro ThermAblator® Endometrial Ablation System |
| Manufacturer: | BEI Medical Systems |
| Address: | 100 Hollister Road, Teterboro, New Jersey 07608 |
| Approval Date: | April 20, 2001 |
| Approval Letter: | http://www.fda.gov/cdrh/pdf/p000040a.pdf |

**What is it?** The Hydro ThermAblator® (HTA) is a computer-controlled system that consists of a pump, valves, a heater canister, and tubing. The system is connected to a hand-held "hysteroscope", an instrument used to see inside the uterus (womb). The HTA uses heat to destroy specific tissue inside the uterus.

**How does it work?** After the patient has received anesthesia, the doctor inserts the hysteroscope and tubing through the vagina into the uterus. The heater canister, which is located outside the body, heats saline fluid (salt water) to a temperature of 194°F (90° C). With the aid of the pump and valves, the heated fluid is circulated through the HTA system and uterus for 10 minutes. The heated fluid directly contacts the innermost layer of tissue (endometrium) of the uterus. This is the layer of fluffy tissue that is shed with the blood when women menstruate. The exposure to heated fluid acts to destroy the endometrium.

**When is it used?** The device is intended for pre-menopausal women whose child-bearing is completed and have a condition called menorrhagia, in which there is excessive uterine bleeding. The device is only used in women whose menorrhagia is due to benign or non-cancerous causes.

**What will it accomplish?** The device was shown to reduce bleeding to normal levels in approximately 68% of the women treated. And it totally eliminated bleeding in approximately 35% of women treated. Side effects of treatment include uterine cramping, abdominal pain, nausea, and vomiting.

**When should it not be used?** The device should not be used on women who have uterine cancer or a pre-cancerous condition, who are pregnant or want to be pregnant in the future, who have had a classical cesarean section, or who have an intrauterine device (IUD) in place. The procedure is not a surgical form of birth control.

**Additional information:** The SSED and Labeling will be available at:
http://www.fda.gov/cdrh/pdf/p000040.html
**Other:** Office of Women's Health website: http://www.fda.gov/womens/
*(Updated 6/4/2001)*