



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

July 31, 1997

**CONSUMER UPDATE:
The Somnoplasty System**

The Somnoplasty System was cleared for marketing on July 17, 1997 via premarket notification (510(k)). Manufactured by Somnus Medical Technologies of Sunnyvale, California, this product uses heat (thermal coagulation) to reduce tissue volume of the uvula, the conical flap of tissue which descends from the soft palate or roof of the mouth. The result is reduction of the excess tissue blocking air passages which may reduce snoring noise in some people.

This is the first electrosurgical system cleared for specific use on the uvula, although several components were previously cleared for general surgical indications. The system operates by placing an electrode under the soft palate which transmits radiofrequency energy to produce a localized temperature increase. After treatment, consequent necrosis and shrinkage of the tissue can improve air flow and potentially reduce snoring noise.

Clinical data submitted by the company demonstrated only a reduction in snoring noise to a tolerable level. It should not be considered an actual cure for snoring. There were no clinical data submitted for the use of the Somnoplasty System to treat sleep apnea or for use of the system on the tongue or throat area. It should be recognized that a sore throat following surgery may necessitate use of non-narcotic OTC analgesics. -

FDA has previously cleared a laser and other surgical devices to reduce soft tissue in this area.