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SCUBA SYSTEM 510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS

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Device Name:	Scuba System
Generic Name:	Hysteroscopic Electrosurgical Device
Classification Name:	Obstetrical and Gynecological Surgical Devices
Classification:	Class II

The Scuba is a bipolar electrosurgical system designed for hysteroscopic surgical correction of myomas, polyps, intrauterine adhesions, and septate uteri. It consists of an electrosurgical generator, a footswitch, three types of electrodes, and a cable connecting the electrode to the generator. The generator is designed to operate from any voltage source between 95-125V and 190-250V a.c. at 50 or 60Hz. It provides six modes of operation (*i.e.*, six waveforms): three vaporize modes, two blend modes (a combination of vaporization and coagulation) and a desiccate mode similar to the traditional coagulation waveform. The generator controls the power settings from 1 to 200 Watts. A green fluorescent display provides up to 16 characters of alphanumeric information, including the selected mode of operation, the power settings, and other messages related to the operation of the generator. Like other electrosurgical equipment, the generator is designed to be located outside the sterile field, with adjustment of operating settings performed by ancillary operating staff.

Three electrode configurations are available: the Spring, Ball and Twizzle. The electrodes are identical in construction except for the distal end and are designed for insertion down a 5 French or larger working channel of commercially available hysteroscopes. The electrodes are operated in a conductive (*i.e.*, saline) fluid environment. When connected to the generator *via* the connector cable, the system detects the type of electrode attached and automatically adjusts the default power settings to the optimal level for each electrode type. The surgeon can change the default power settings as required. The electrodes are provided as sterile, single-use items. The connector cable is steam sterilizable, designed for twenty times reuse.

The Scuba is intended to be used for tissue cutting, vaporization and desiccation as required or encountered in gynecologic hysteroscopic electrosurgical procedures for excision of intrauterine myomas and polyps, lysis of intrauterine adhesions, and excision of uterine septa.

Results from non-clinical studies including *in vivo* studies using the porcine animal model, biocompatibility testing, and clinical studies have shown the Scuba system to be safe and effective in vaporizing and coagulating uterine tissue. In the porcine animal studies using a stomach test model and a skin flap model in live swine, the Scuba device was shown to vaporize and coagulate live tissue. The same electrode used for vaporization was shown to effectively desiccate live tissue and prevent bleeding.

In clinical studies using extirpated uteri, the Scuba system was compared to monopolar electrosurgery and laser surgery. The Scuba system was found to be as effective in cutting and coagulating uterine tissue as the monopolar and laser surgery devices. In one extirpated uteri study using ten uteri, the Scuba and Erbotom Generator were compared side by side in each uterus. Both devices were effective in excising and coagulating uterine tissue. When using the small Scuba electrode the field of view remained clear and all structures were easily visualized. There was no accumulation of debris to obstruct vision. Histological evaluation of the tissue effects showed both devices performed similarly. Serosal temperature measurements recorded throughout the procedure showed no significant difference in uterine temperature for the two devices.

These studies have demonstrated that the Scuba system is substantially equivalent to the Erbotom Generator used with the Karl Storz Hysteroscopic Resectoscopy Accessories (electrodes). Both devices have the same intended use and similar tissue effect. The bipolar features of the Scuba system do not pose new safety questions when compared to currently marketed electrosurgery generators and electrodes. There are actually fewer safety issues with bipolar surgery than with monopolar surgery. Bipolar surgery has been used safely for many surgical procedures, although it is not currently marketed for intrauterine electrosurgery.