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**510(k) Summary**

**EMS LITHOVAC SUCTION/ASPIRATION PROBE**

**1. Sponsor/Applicant**

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**2. Device Name**

Trade or Proprietary Name:	LITHOVAC Suction/Aspiration Probe
Common/Usual Name:	Suction/aspirator, evacuator
Classification Name:	Gastroenterology-urology evacuators

**3. Identification of the Predicate or Legally Marketed Device(s) to Which Equivalence is Being Claimed**

Uromat Suction Pump/Calcuson Ultrasonic Lithotrite System, the Olympus Ureteromat Pump/LUS Lithotripsy device, and numerous other vacuum aspiration systems such as the Corson Disposable Suction Irrigation Probe, and the Nezhad-Dorsey Hydro-Dissection Reusable Suction Irrigation Probe.

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#### 4. Device Description

The EMS SA LITHOVAC Suction/Aspiration Probe is intended to be used to aspirate out urinary calculi, fragments and debris using a standard vacuum source, i.e. a regulated wall vacuum, a standard suction pump, or a peristaltic pump which can supply up to -0.8 bar vacuum. Accessory adapters are provided to permit it to be used to aspirate urinary stone fragments or debris produce during fragmentation of urinary stones with the EMS Swiss LITHOCLAST lithotripter.

The LITHOVAC consists of a suction tube with a trumpet valve, and accessories for connecting the EMS Swiss LITHOCLAST handpiece and probe to the suction tube.

The LITHOVAC suction tube is made of type 304 stainless steel and is available in four diameter/length combinations as follows:

- 1.6 mm OD/445 mm length disposable sterile
- 1.6 mm OD/555 mm length disposable sterile
- 3.5 mm OD/460 mm length reusable non-sterile
- 4 mm OD/430 mm length reusable non-sterile

The size of the suction tube is chosen according to the size of the endoscope to be used, e.g., the 4 mm LITHOVAC Probe is used through a 12 Fr or greater endoscope.

#### 5. Intended Use

The Electro Medical Systems SA LITHOVAC Suction/Aspiration Probe is designed for the suction and aspiration of urinary tract calculi fragments through rigid or semi-rigid endoscopes. It can be used alone, or it can be used during and after fragmentation of urinary tract calculi with the EMS Swiss LITHOCLAST intracorporeal lithotripter. It is specifically designed so that an EMS LITHOCLAST lithotripsy probe can be inserted through the LITHOVAC suction tube so that stone fragments and debris can be aspirated through the LITHOVAC suction tube simultaneously with lithotripsy.

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**6. Technological Characteristics**

The EMS LITHOVAC Probe technological characteristics are the same as the predicate devices in that they are suction/aspiration devices that consist of probes or tubes for evacuating fluids and debris during or after lithotripsy treatment.

**7. Performance Testing**

Animal studies were performed in the pig model to assess the effectiveness and the potential for injury of the EMS LITHOVAC Probe used with the EMS LITHOCLAST Lithotripter in fragmenting and aspirating stones in the pig bladder and ureter.

The LITHOVAC/LITHOCLAST Probes were used to fragment and aspirate four stones in the pig bladder using maximum LITHOVAC suction. Immediately after treatment, only mild ecchymosis was noted at the areas where the stones were treated.

The LITHOVAC was then applied directly to three separate areas of the bladder mucosa at maximum suction for 10 seconds each. Only, mild ecchymosis was observed. At one week post-treatment, the bladder was harvested and showed no macroscopic or microscopic perforation, or fibrosis. The urothelium was intact demonstrating that even with the minimal mucosal damage immediately post-treatment, complete regeneration of normal urothelium had taken place within one week.