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The FemRx Focused Monopolar (FMP) OPERASTAR™ System is identical to FemRx's currently marketed OPERASTAR™ System resectoscope in terms of outward appearance and basic tissue cutting, ablating and morcellating mechanism (electrocautery wire / Star loop and morcellator internal to the fluid return path). That is, high frequency electrocautery current is applied to a single active electrode to either cut or coagulate tissue which is subsequently chopped up and aspirated via a morcellator internal to the fluid return path.

The FMP OPERASTAR System differs from our previously cleared device in that the return electrode has been moved from outside of the patient body (dispersive electrode pad attached to the patients back or leg) to the metallic body of the device (outer tube/housing the morcellator). (Reference the Device Description section of this submission for an "insulation diagram" and schematic drawing providing a diagrammatic representation of the electrical circuit effect of moving the return electrode.) This change in return electrode location makes it possible to use (indeed requires the use of) a conductive irrigant solution such as normal saline (0.9% NaCl). The use of an isotonic solution eliminates significant potential complications associated with non-isotonic solutions (e.g., Mannitol, Sorbitol, Glycine).

The FMP OPERASTAR System differs from currently marketed bi-polar devices in that it continues to have a single active electrode (wire loop or Star loop) as opposed to two active electrodes. The return electrode (the metallic outer Morcellator housing of the device) has such a large surface area relative to the active electrode that there can be no tissue coagulating (much less cutting or ablating) effect at its surface. Current densities near the surface of the morcellator housing have been measured to verify this physical impossibility.

In vitro and extirpated uteri studies comparing the resection and ablation performance of the Focused Monopolar device with the predicate confirmed that resection and ablation characteristics are substantially equivalent to currently marketed devices.