

510(k) Premarket Notification
Maher Abdominal Wall Elevator
Cook Urological, Incorporated and COOK OB/GYN[®]

K960878

J. 510(k) Summary of Safety and Effectiveness

Submitted By:

K-960878

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Device:

Trade Name: Maher Abdominal Wall Elevator

Proposed Classification Name: Laparoscope, General and Plastic Surgery 79 GCJ

Predicate Devices:

The Maher Abdominal Wall Elevator is substantially equivalent to predicate abdominal wall elevators in terms of indications for use, design, construction and materials equivalence. Specifically, this device is similar to the Mediflex[®] Bookler[®] A.W.E.L.[™] Abdominal Wall Elevator (K943614) manufactured by Mediflex, 250 Gibbs Road, Islandia, NY 11722.

Device Description:

The Maher Abdominal Wall Elevator is used to elevate/retract the abdominal wall for low pressure laparoscopic procedures. The device is intended to be used after the establishment of a pneumoperitoneum. The device is manufactured entirely from stainless steel. Stainless steel is widely used in the medical field and biocompatibility is assured.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. This device will undergo packaging similar to the devices currently marketed and distributed by Cook Urological, Incorporated and COOK OB/GYN[®]. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.