Medspira Receives FDA 510K Clearance for mcompass Biofeedback/Pelvic Floor Retraining Device

Provides Solution for Patients Suffering in Silence

October 7, 2015—Minneapolis— Medspira has received US Food and Drug (FDA) 510K clearance for its mcompass biofeedback/pelvic floor retraining system. Pelvic floor therapy coaches/retrains patients to properly utilize their pelvic floor muscle functions to help control constipation or fecal incontinence symptoms.

Utilizing the same hardware and software platform as their previously FDA approved diagnostic anorectal manometry system the mcompass biofeedback/pelvic floor retraining system features, an accurate, easy to perform and practical solution for pelvic floor health for a wide variety of medical specialists. In addition to colorectal surgeons, URO/GYNs, OBGYNs and gastroenterologists, Medspira will market the device to physical therapists to ensure full access to all patients.

"Affecting every aspect of life, fecal incontinence and constipation is a problem that is widely undiagnosed and untreated," says Jim Quackenbush, CEO from Medspira. "Well over 15 million Americans suffer from these debilitating issues and the majority of them in silence. The goal of our innovative diagnostic and now treatment mcompass system is to give patients access to a solution to these problems."

"There are a variety of high cost, invasive, and physically demanding treatments available, but our goal along with a variety of industry experts was to design a solution that can help the patient help themselves. With no costly surgery, no implants, and no injections biofeedback/pelvic floor retraining allows the patient to retrain their muscles and their mind to work together again."

The intuitive and user-friendly mcompass system is comprised of three simple components—a disposable catheter, mobile tablet PC workstation and wireless FOB. Built-in software prompts guide providers through the testing and retraining process. The device is ready for use within seconds, and results display in real time on the device's tablet PC workstation. The full data packet can be emailed to specialists for interpretation, if needed, in a single click using the device's built-in WiFi connectivity.

"Many traditional biofeedback/pelvic floor retraining devices on the market today utilize EMG monitoring" explains Tony Doherty, Director of Sales. "The team of specialists we worked with wanted to use pressure instead of electric current to monitor the patient's recruitment of the pelvic floor during biofeedback/pelvic floor retraining. The idea is to use the same measurement method as anorectal manometry testing. This allows you to get an apples to apples comparison from the initial diagnostic testing and what improvement during biofeedback/pelvic floor retraining therapy you are seeing."

About Medspira

Since 2009, Medspira has worked with leading medical institutions to develop and market medical devices that provide cost effective diagnosis and treatment for a variety of conditions. Its highly focused distribution model addresses United States and worldwide markets. Products are produced in partnership with world-class, FDA approved and ISO 13485 registered manufacturing facilities.