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ASIA EDITION

Itamar Medical's WatchPATÃ¢â??Â¢ One receives FDA 510(k) Clearance

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New system expands WatchPAT access to additional sleep centers by reducing infrastructure needs and eliminating capital requirements; also reduces infection risk for in-patient sleep apnea testing



Itamar Medical Ltd., a company that develops, manufactures and markets non-invasive diagnostic medical devices for sleep apnea with a focus on the cardiology market, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration for WatchPAT One, the latest innovation of its WatchPAT technology and the first and only fully disposable Home Sleep Apnea Test (HSAT).

WatchPAT One incorporates the technology and comfort advances of WatchPAT 300, which received 510(k) clearance in August 2018 and was launched in March 2019.

Gilad Glick, President and Chief Executive Officer of Itamar Medical said, “WatchPAT One is ideally suited for clinics and practices that recognize the value of HSAT but have limited resources, infrastructure or capital to invest in acquiring or managing our reusable WatchPAT products. WatchPAT One offers patients and physicians the same simplicity, accuracy and reliability as WatchPAT 300 without the need for return shipping, downloading, cleaning or preparation for the next study. We expect the availability of a disposable WatchPAT system will improve patient access by increasing the number physicians able to offer our cuttingedge technology to their patients. Additionally, as a disposable HSAT, WatchPAT One may have particular utility in the inpatient setting, where transmission of infection through reusable medical devices is a significant concern.”

With WatchPAT One, patients pair the WatchPAT device to their smartphone using Itamar’s proprietary app. Sleep study data are collected during the test and automatically sent to CloudPAT™, Itamar’s secure server. Once the test is complete, a comprehensive report using WatchPAT’s True Sleep Time, Sleep Architecture and Central Plus algorithms is automatically generated and sent to the prescribing physician. The patient then disposes the WatchPAT device. WatchPAT One utilizes the same reimbursement codes as Itamar Medical’s other outpatient WatchPAT studies.