KarmelSonix

"Wheeze Rate – A New Paradigm in Asthma Management"

COMPANY ANNOUNCEMENT

WheezoMeter™ Granted FDA Clearance

24th September 2009: The Directors of KarmelSonix Ltd (KSX or the Company) wish to announce the grant of marketing clearance 510k (k090863) by the US Food and Drug Administration (FDA) to the WheezoMeter™. The WheezoMeter™ can now be sold for use by all healthcare professionals in the US such as physicians (General Practitioners, Pulmonologists, Paediatricians, Asthma and Allergy Specialists etc), nurses (including school nurses and asthma nurses), Emergency Medical Personnel (EMS) and respiratory therapists (RT).

The WheezoMeter™ can be used to measure the WheezeRATE™ of patients over a short span of time (30 sec) to document the patient's extent of wheeze and his/her response to treatment (before and after a bronchodilator). The WheezoMeter™ has previously been cleared for use in Europe (CE Mark) and Australia (TGA). The Company plans to seek FDA clearance for use of the WheezoMeter™ by patients and parents (home use) by prescription and when purchased over the counter (OTC) in due course.

Sale of the WheezoMeter™ to the professional markets in the US will be through US national distributor(s) who specialize in sales to the hospital-based practitioners, RTs, EMS personnel as well as to doctors' offices and community-based allied healthcare personnel.

"This major milestone was achieved through extensive and concerted effort by KarmelSonix' technology and regulatory personnel" commented the Company's General Manager Prof. Noam Gavriely. He added that "This clears the way for expansion of our marketing and sales activities in the large US market to the clinic-based community health care where more than 95% of asthma patients are being cared for. This will facilitate familiarising practitioners with the concept of quantitative and objective wheeze assessment in the form of the WheezeRATE™. This step opens the door to introduction of the WheezoMeter™ for use by the general patient population."

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KarmelSonix Ltd. focuses on supplying innovative non-invasive acoustic tools for disease management of asthma and related pulmonary disorders. Asthma affects 6-16% of the population in developed countries with a cost exceeding $US15 billion in the US alone.

Acoustic Asthma Management is a breakthrough in monitoring of the asthmatic patient of all ages, including the very young, very old and others who cannot perform currently available tests. The technology that comes from extensive R&D and clinical validation in the US, Israel and Australia, facilitate continuous monitoring of patients at home, in the ICU and even during sleep. The company is focused on early commercialization of its products with special emphasis on the European and North American markets.

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Re: K090863
Trade/Device Name: Personal Wheezometer™
Regulation Number: 868.1900
Regulation Name: Diagnostic Pulmonary Function Interpretation Calculator
Regulatory Class: II
Product Code: BZM
Dated: August 28, 2009
Received: September 1, 2009

Device Name:	**PERSONAL WHEEZOMETER™**
Indications for Use:	The **PERSONAL WHEEZOMETER™** is intended for quantifying the presence of wheezing. This device should be used under the direction of a physician or licensed healthcare professional for monitoring acoustic pulmonary functions.

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