Corsens Medical Ltd., Announces Filing of a 510(k) Pre-Marketing Notification with the US Food and Drug Administration for the Corsens Cardiac Monitor

The Cardiac Monitor is intended to detect heart contractility parameters required for continuous heart function monitoring

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TEL AVIV, Israel—(BUSINESS WIRE)—Corsens Medical Ltd., today announced that it has successfully completed filing of a Pre-Marketing Notification (510(k)) with the US Food and Drug Administration (FDA) for its Corsens Cardiac Monitor.1,2

The company is seeking the following indications statement for the Corsens Cardiac Monitor: "CORSENS records vibrational waveforms produced by the heart contractions and transmitted to the chest wall. CORSENS may be used as a tool to measure the timing of part of the events in the cardiac cycle." The Corsens Cardiac Monitor is designed to detect cardiac contractility parameters via a series of acoustic, accelerometers and cardiac rhythm non-invasive sensors arrayed on the patient's chest.

Alon Tomas Marmor, MD, previously Clinical Professor, Faculty of Medicine, Bar-Ilan University, Israel, commented, "Acute myocardial infarction (MI) remains a leading cause of morbidity and mortality worldwide. Only 15-20% of the patients who suspect that they are having an MI and present to an emergency department have pain of cardiac origin. There is an unmet need for a device that can provide a non-invasive and quick assessment of cardiac ischemia." Dr. Marmor continued, "The Corsens Cardiac Monitor has the potential to detect myocardial contractility changes which can direct clinical management of cardiac ischemia."

Evgeny Fizgeer, CEO of Corsens Medical Ltd, commented, “We are thrilled to have reached this important milestone in the development of the Corsens Cardiac Monitor with the filing of our Pre-Marketing Notification (510(k)) with FDA. We anticipate significant clinical interest for this innovative technology in the markets where the Corsens Cardiac Monitor will be cleared for commercial distribution. This is the first in a series of regulatory filings, while we continue the development of the Corsens Cardiac Monitor.”

About Alon Tomas Marmor, MD

Alon Tomas Marmor, MD, most recently held the position of Full Clinical Professor, Faculty of Medicine, Bar-Ilan University. Dr. Marmor has held the positions of Clinical/Associate Professor, Faculty of Medicine at Bar-Ilan University and Technion, Haifa. Dr. Marmor has held administrative posts as Head of Heart Institute, Head of Cardiology Division, and Chairman of Cardiology Department, Ziv Government Hospital, Safed. Dr. Marmor has served as Principle investigator in more than 120 multicenter international clinical trials since 1988.

About the Corsens Cardiac Monitor
The Corsens Cardiac Monitor is designed to detect cardiac contractility parameters via a series of acoustic, accelerometers and cardiac rhythm non-invasive sensors arrayed on the patient's chest. The Corsens Cardiac Monitor is intended to provide continuous monitoring of the heart activity with the assessment of patient's condition relative to their cardiac rhythm. Continuous monitoring is critical for detection of myocardial infarction. Rapid detection is critical for patient survival. In previous studies, conducted at the Ziv Medical Center, Safed, Israel\(^4\), the Corsens Cardiac Monitor demonstrated stable, reproducible, and consistent cardiac contractility changes in patients undergoing heart catheterization procedures\(^5\).

**About Corsens Medical, Ltd.**

Corsens Medical, Ltd., founded in October, 2013, is a development stage medical device company based in Tel Aviv, Israel, developing the Corsens Cardiac Monitor. The Corsens Cardiac Monitor is intended to participate in the global cardiac monitoring and cardiac rhythm management devices market which is expected to reach $12.5B by the end of 2020 growing at a CAGR of around 13.2% from 2014 to 2020\(^6\).

\(^1\) Patents pending  
\(^2\) The Corsense Cardiac Monitor is not approved for sale in the US or Europe  
\(^3\) Dr. Marmor is a founder and Chief Medical Officer of Corsense Medical, Ltd.  
\(^4\) Ziv Medical Center was established in 1910 in Safed, affiliated to Bar-Ilan University's Faculty of Medicine. Research cooperation takes place with the Faculty of Medicine and with Migal, the Galilee Research Institute.  

http://www.microdel.co.il/cardiac.asp

**Contacts**

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