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CLEVEMED RECEIVES FDA CLEARANCE TO MARKET WIRELESS MOVEMENT DISORDER MONITOR

CLEVELAND, **OHIO**, **May 1**, **2007** – Cleveland Medical Devices Inc. (CleveMed) received Food and Drug Administration (FDA) clearance to market Kinesia[™], a quantitative motor assessment system. Kinesia is a compact wireless system that uses accelerometers and gyroscopes to monitor three-dimensional motion. The device is worn on the wrist and finger of the patient and can be used to more conveniently monitor upper extremity movement disorder symptoms and their fluctuations. Motion and electrical muscle activity (EMG) information from the patient is wirelessly telemetered to a computer for display and analysis. The Kinesia software also integrates videos which guide the patient through tasks known to elicit symptoms, similar to instructions given by a physician when evaluating upper extremity motor symptoms.

Movement disorders, such as Parkinson's disease and essential tremor, affect millions of people worldwide. Associated with these disorders are motor symptoms, most commonly tremor, bradykinesia (slowed movements) and dyskinesias (exaggerated, involuntary movements) that can change rapidly and affect quality of life for many individuals. There is currently extensive research to develop new therapies to treat these disorders. Dr. Peter LeWitt, Director, Division of Parkinson's Disease and Movement Disorders for Henry Ford Health Systems and Kinesia user said, "Progress in developing new therapies needs equipment that can reliably quantify movement and Kinesia has performed very well in clinical and research settings for high-quality physiological recordings of tremor and dyskinesia."

Kinesia, formerly ParkinSense[™], is a device developed by CleveMed to monitor these symptoms either in the clinic or at home. This is important because over the course of a day, a patient's symptoms can include dramatic shifts from tremor to dyskinesia making activities of daily living difficult. More continuous monitoring and tracking of symptom fluctuation patterns can provide better insight on how symptoms respond to pharmaceutical drug interventions or procedures such as deep brain stimulation.

"Objectively quantifying motor symptoms of movement disorders such as Parkinson's disease and essential tremor is critical to understanding changes in response to interventions. Symptom fluctuation patterns are difficult to capture during an office visit", said Joseph Giuffrida, PhD, Director of the Division of Movement Disorders at CleveMed. "The Kinesia system provides more continuous monitoring through a novel, patient worn technology platform that wirelessly transmits motion and muscle activity anywhere. The compact, untethered engineering design allows great flexibility for clinical measurements and research."

While the current system provides a novel tool for quantifying movement disorder symptoms, CleveMed will continue to improve the system over the next year. A clinical study comparing

Kinesia quantitative outputs to clinician scores for Parkinson's disease motor symptoms of tremor, bradykinesia, and dyskinesia is in its final stages. The system has shown good correlations between the device output and clinician evaluation results with forty patients while an additional twenty patients are planned. Using that data, CleveMed plans to integrate automated symptom detection and scoring features into the software and provide symptom severity reports to clinicians. Additionally, CleveMed plans to package the reports into a webbased application that will allow clinicians to retrieve reports directly from a patient's home.

The Division of Movement Disorders at CleveMed is focused on quantifying movement disorder symptoms and providing home based therapy aimed at restoring function. The movement disorder product line includes a series of products for improving the quality of life for people living with movement disorders. KinetiSense[™] is a device developed using the same technology platform as Kinesia. It is used for research applications such as gait research, physical therapy applications and balance and posture research. Also in development is a home therapy device for children with cerebral palsy and persons who have suffered a stroke. The system uses a combination of functional electrical stimulation, motion sensors and EMG to aid in therapy to restore motor function.

About CleveMed – CleveMed was founded with the goal of developing innovative telemetry devices for a variety of medical applications. Today, CleveMed is developing and pioneering the use of novel wireless monitoring systems for high growth neurology and rehabilitation applications, including brain monitoring, sleep disorders and movement disorders. Through these innovations, CleveMed has developed a growing range of products that address the needs of the medical, research and academic communities.

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