Anuncia Medical, Inc., receives FDA clearance for the ReFlow® System Mini for the treatment of patients with hydrocephalus

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Anuncia Medical, Inc. →
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SCOTTSDALE, Ariz., Sept. 29, 2022 /PRNewswire/ -- Anuncia Medical, Inc., announced that the U.S. Food and Drug Administration (FDA) cleared the ReFlow® System Mini for the treatment of patients with hydrocephalus and other cerebrospinal fluid (CSF) disorders that require shunting.

Anuncia Medical, Inc., announced that the ReFlow® System Mini received 510(k) clearance for the treatment of patients with hydrocephalus and other cerebrospinal fluid (CSF) disorders that require shunting.

Anuncia Medical announced FDA clearance of ReFlow® System Mini for the treatment of cerebrospinal fluid (CSF) disorders.

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The FDA 510(k) clearance allows Anuncia Medical to commercialize the ReFlow® System Mini in the US. The cleared ReFlow® System Mini is indicated to noninvasively provide a flush of the ventricular catheter to restore, increase, or maintain CSF flow in a shunt. Under the care, direction, and instruction of the treating physician, the ReFlow® System Mini may be used as directed for noninvasive flushing by a trained healthcare professional in-clinic or by trained caregivers or adult patients at home.

"This is very exciting news for Anuncia and for the hydrocephalus community," said Elsa Chi Abruzzo, **President & CEO** of Anuncia. "The ReFlow® System Mini is the result of important feedback received from clinician validation of the Gen 1 product. It is a big step in Anuncia's vision to support neurosurgeons who believe the Mini can improve outcomes and patient's lives. Our efforts to evolve hydrocephalus care will continue with clinical trials to evaluate the potential of Mini to extend shunt life and significantly reduce the large unmet medical need of solving repeat revision brain surgeries."

In addition, this week Anuncia Medical was honored by AZBio as a "2022 Fast Lane Company for the progress they are making in answering the call from people with hydrocephalus and growing their team to deliver on solutions. Patients and their care teams call on our health innovators to address areas of care where new and better solutions are needed," said **Joan Koerber-Walker, President & CEO of AZBio.**

The costs of, often-emergent, revision surgeries to restore CSF flow and alleviate painful symptoms, present a heavy emotional and financial burden to patients, families, and healthcare facilities. **Ramin Eskandari, MD MS, Chief of Pediatric Neurosurgery at the Medical University of South Carolina**, remarked, "The clearance of the ReFlow System Mini gives that same game-changing option to those patients with the highest need and most to gain: the infants and babies who were too small to have the original ReFlow system. Now with the Mini, neurosurgeons can look patients and their families in the eyes and tell them we finally have options that may give you better care and improve the quality of your life."

About the ReFlow® System Mini
The ReFlow® System Mini is designed to help patients with CSF disorders, such as hydrocephalus, a debilitating and life-threatening condition affecting more than 30 million patients worldwide.

The ReFlow® System Mini has a ReFlow® Mini Flusher and ReFlow® Ventricular Catheter. The Mini Flusher connects directly to the Ventricular Catheter. Both are implanted under the scalp and connected to a flow regulating shunt valve (not provided as part of the ReFlow® System Mini). The ReFlow® Mini Flusher may be used noninvasively (without surgery) as prescribed by the treating physician to send a small, controlled flush of fluid toward Ventricular Catheter in an effort to push out any blockages from catheter flow holes. If the catheter flow holes remain

blocked, the flush opens the 'relief membrane' backup feature of the ReFlow™ Ventricular Catheter to make an additional fluid pathway and re-establish flow. The ReFlow® System Mini is not intended to change diagnosis, treatment, or follow-up of patients with proximal catheter occlusions.

About Anuncia Medical, Inc.

Anuncia is a medtech start-up innovating CSF Management and Neurocritical Care therapeutic and monitoring devices. Our clinically validated, non-invasive, devices have US FDA Breakthrough Device designation for the prevention of shunt occlusions (at-home or in-clinic) to reduce or eliminate the high rate of repeat revision brain surgeries in patients with hydrocephalus and other CSF disorders.

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