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Bresotec Medical completes its 510(k) submission for the BreoDX1 sleep apnea testing system.

Toronto, Ontario: Bresotec Medical today announced its submission to the FDA, following the completion of their clinical trials, with the assistance of Hogan Lovells, a law firm with extensive experience and insights gained from working in some of the world's most complex legal environments and markets. The submission was based on clinical trials that were completed with a total of 164 patients at McMaster University in Hamilton, Ontario and in South Carolina at Bogan Sleep Consultants, LLC. Dr. Raymond Gottschalk was the Principal Investigator. Dr. Gottschalk is a Sleep Disorders Specialist, Respiriologist, and the Medical Director at the Sleep Disorders Clinic in Hamilton, ON.

This is a major milestone for Bresotec on its mission to launch their home sleep apnea testing device in the U.S. later this year.

Bresotec is an innovative medical technology company that's providing sleep healthcare professionals with a better way to diagnose sleep apnea. The Bresotec advantage is its proprietary approach of gathering sleep data using breath sounds, a more direct and natural approach than used by other home systems. The result is the world's easiest at-home test designed to deliver accuracy comparable to a sleep lab.

Introducing a better way to test for sleep apnea