

NaviENT Receives FDA 510(K) Clearance

ClaroNav announces that NaviENT, its Surgical Navigation System, received FDA 510(K) clearance.

TORONTO, ONTARIO, CANADA, September 26, 2017 /EINPresswire.com/ -- [ClaroNav](#) is pleased to announce that it has received FDA 510(K) clearance from the Food and Drug Administration (FDA) to market and sell [NaviENT](#) in the United States. NaviENT had previously been granted CE mark for the European market and Health Canada approval for the Canadian market in 2016.

NaviENT, a computer-assisted surgical navigation system, is like a GPS for the surgeon to navigate inside the patient skull. It provides three-dimensional visualization and helps surgeons with finding their ways inside the patient sinuses and avoid critical structures such as the optic nerve and brain, while safely navigating their way to the diseased area.

Sinusitis is inflammation of the sinuses, which are air-filled cavities in the skull. Sinusitis is one of the most prevalent of human diseases, about 29 million Americans are affected by the chronic form of the rhinosinusitis disease with annual direct cost of over 4 billion dollars. Approximately 500,000 of these patients undergo a minimally invasive endoscopic sinus surgery procedure. The goal of the surgery is to restore ventilation and drainage while preserving mucosa. NaviENT is a three-dimensional mapping system that combines computed tomography (CT) scans and real-time information about the exact position of surgical instruments using a stereoscopic optical tracking system. In this way, surgeons can navigate their surgical instruments through complex sinus passages and provide surgical relief more precisely. Study shows that surgical navigation systems would allow more complete dissection, obviating the need for revision surgery. It also results in cost saving by shortening length of hospitalization compared to non-navigated surgeries. The American Academy of Otolaryngology - Head and Neck Surgery ([AAO-HNS](#)) endorses the use of image-guided surgery for many functional endoscopic sinus surgeries and skull base procedures.

"Surgical Navigation system is a precious aid in primary surgery and its benefits are widely accepted among neurosurgeons and otolaryngologists. Its 3D anatomical structure localization and visualization capability assists the surgeons to target specific anatomy and avoid complications in highly variable sinus anatomy. However, despite its obvious advantages, many surgeons are hesitant in adapting the technology, blaming its cumbersome operation and high price tag." said Ahmad Kolahi, CEO of CKI, a subsidiary of ClaroNav "NaviENT is an innovative navigation system designed in close collaboration with experienced rhinologists to address shortcomings of the current navigation



NaviENT Surgical Navigation System

systems. Our primary goal is to offer an intuitive, accurate and affordable state-of-the-art ENT navigation system and make it standard-of-care in the ENT field."

For more information about the NaviENT, please visit www.claronav.com/navient

About ClaroNav

ClaroNav is a medical device hardware and software company headquartered in Toronto, Canada, and is represented worldwide by authorized distributors. ClaroNav is dedicated to innovation and developing state-of-the-art surgical navigation systems to enable surgeons to confidently make more informed decisions for better patient outcomes. For more information, visit www.claronav.com.

Contact

ClaroNav Inc.

1140 Shepard Avenue West

Toronto, Canada, M3K 2A2

Phone: + 1 (647) 951 1525

Website www.claronav.com

Email: info@claronav.com

ahmad kolahi

CKI (A Subsidiary of ClaroNav Inc.)

6479511525

email us here

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