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IACBE Fall Case Competition 2019
Project: Munevo Go-To-Market Strategy

Executive Summary

Simply nod and drive! Munevo drive allows people of any age greater independence by being the first wheelchair control that uses smart glasses for hands-free driving via a simple head tilt. Common alternatives include chin-control, sip & puff, head array and other wearable devices but can be unhygienic, limiting, and hard to adapt to. There are approximately 6 million power wheelchair users in the U.S. and each year more than 10,000 people require a special control for their wheelchair. In 2018, 1.825 million wheelchair users were age 65+, 17.4% of working age wheelchair users were employed, and there was an expected \$3.9 billion in the power wheelchair market due to the large need among the baby boomer generation (Wheelchair Facts, Numbers and Figures [Infographic], 2015).

Due to the complexity of the U.S. Healthcare system and the abundance of insurance companies, it is our recommendation that Munevo obtain U.S. Food and Drug Administration (FDA) approval for the Munevo Drive glasses and begin demonstrating and marketing their product through key foundations and institutions, attending medical conferences, and selling their product to Durable Medical Equipment (DME) distributors, hospitals, and foundations. This will establish and improve their market base here in the U.S. and allow them time to obtain contracts with insurance companies to sell directly to the patient in the future.

FDA Approval

The FDA's role is to ensure the safety, efficacy, and security of a number of U.S. products, such as medical devices, drugs, food, and cosmetics (FDA.gov). Before entering the American market, manufacturers need approval from the FDA. There are several routes that are dependent upon the class of medical device. A 2017 report to Congress on the Medicare and Healthcare Delivery Systems outlines the different classes of medical devices. The Munevo glasses would most likely fit into the category of Class II, which includes powered wheelchairs. For Class II FDA approval, manufacturers must fill out a 510k Premarket Notification. The only stipulation for consideration for Class II designation is the device must demonstrate it is "substantially equivalent" to one already on the market. The manufacturer can choose the device to which it most closely aligns scrolling through the FDA database. The average turnaround time for a Class II approval route is 3-6 months, although 79-85% are approved within 3 months (Medpac Report 2017). Once manufacturers obtain approval from the FDA, they are able to sell medical devices to hospitals, physicians, and nursing homes rather than individual consumers. It is important to note that Class II FDA approval does not necessarily mean that insurance companies will cover the cost of the glasses for patients.

Key Foundations and Institutions:¹

- American Spinal Injury Association (ASIA)
- American Spinal Research Organization (ASRO)
- Multiple Sclerosis Foundation (MS Focus)

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- The ALS Association
- The National Institute of Neurological Disorders and Stroke (NIH)
- Christopher and Dana Reeve Foundation

Key Hospitals and Departments^{1,2}

- Shriner's Hospitals for Children- 22 main locations across the country/ St. Jude Children's Research Hospitals- 8 locations across the country
- Department of Defense/Veteran's Administration (Military-specific/located at every base in the world)
- Hospital Corporations of America (HCA)- 166 locations
- Universal Health Services, Inc.- 350+ locations

Top Wheelchair Manufacturers in the U.S. in 2018

- 21st Century Scientific Inc., Invacare Corp., Ottobock Healthcare GmbH, Permobil AB, Pride Mobility Products Corp., Sunrise Medical Inc., GF Health Products, Inc., Hoveround Corp., Levo.AG, Medical Depot Inc., Merits Health Products Co. LTD., Meyra Wilhelm Meyer GmgH & Co. KG

Medical Conferences to Attend/Demo⁴

- 2020 Forbes Summit (as scheduled-Congratulations!)
- 2020 BIOMEDevice Boston, MA
- 2020 Southeast MedTech Forum

Podcasts and Interviews

- Christopher and Dana Reeves Foundation Blog
- Facingdisabilities.com (blog)
- SCI Life Uncovered Podcasts at spinalcord.com
- Talk to Defeat ALS - ALS Association

Thank you for sharing your innovative product with us and we hope that you find the answers that you are searching for.

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Footnotes:

¹For more information regarding the key foundations and institutions visit: <https://asia-spinalinjury.org/about/mission/>; <https://www.csro.com/research/>; <https://www.christopherreeve.org/living-with-paralysis/stats-about-paralysis>; <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Cerebral-Palsy-Hope-Through-Research>; <https://msfocus.org/About-Us.aspx>; <https://www.braintrauma.org/about>

²Medicare provides wheelchair reimbursement for patients. Visit www.MySeniorSource.com for the 12-step process.

³Top 12 Powered Wheelchair Manufacturers and Distributors in 2018. Visit <https://blog.technavio.com/blog/top-12-powered-wheelchair-manufacturers-and-distributors> for the list.

⁴For a full list of 2020 medical conferences, visit <https://theconferencewebsite.com/medical-conferences-2020> or <https://medicaldeviceevents.com/medical-device-conferences/top-events-meetups/>