Canary Medical's Smart Spine Lumbar Cartridge Granted FDA "Breakthrough Device" Designation

- *Smart Spine Lumbar Cartridge is the fourth Canary Medical product to receive Breakthrough Designation through the FDA Breakthrough Devices Program*
- *Lumbar Cartridge represents Canary Medical's first smart sensor application for Spine procedures*

VANCOUVER, BC – May 29, 2024 – Canary Medical, a medical data company focused on the development and commercialization of its patented implantable sensor technology and complementary data and analytics ecosystem, today announced FDA's grant of "Breakthrough Device" designation[1] for its Canturio® Lumbar Cartridge (canturio®*lc*) with Canary Health Implanted Reporting Processor (CHIRP®) System. The canturio®*lc* is intended for use with a Lumbar Interbody System for lumbar spinal fusion from L1-S1. The cartridge is designed to provide objective kinematic data from the implanted medical device during a patient's post-surgical treatment of symptomatic degenerative disc disease. The transmitted data will be used to remotely monitor the progression of fusion and facilitate the early detection of clinically significant instability, partial fusion and non-fusion.[2]

Like the currently commercialized Canturio® Tibial Extension (canturio®*te*), the canturio®*lc* is intended to collect various kinematic measures for at least 10 years and pool the data from each of the multiple parameters across the patient population. Canary's data platform will provide clinicians with frequent, objective aggregate population data for each patient's activity levels and kinematics to rank each patient's performance versus their peers based on age group, gender and time since surgery. Clinicians will be able to access and use this daily functional information to help determine whether to augment their in-office patient examinations and/or to update their patient's care plan in the year following surgery.

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[1] The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The Breakthrough Program is intended to help patients have more timely access to medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

[2] The kinematic data from canturio®*lc* is an adjunct to other physiological parameter measurement tools applied or utilized by the physician during patient treatment post-surgery.

"The approval of canturio®*lc* is the fourth time in-a-row that a Canary Medical product has received Breakthrough Device designation from the FDA, an unparalleled accomplishment in our industry. First, we received breakthrough designation for our smart knee, followed by hip and shoulder applications, and now, our smart spine application. I would like to congratulation the entire Canary team for their continued excellence," said Bill Hunter, M.D., Founding Member and Chief Executive Officer of Canary Medical.

"It is also notably Canary's first smart spine offering and the Company's first FDA Breakthrough Designation outside of the large joint space, which is momentum we intend to maintain. Based on the results we have seen with our current "smart" knee product, this designation is also great news for future lumbar spinal fusion patients. We look forward to securing an innovative spine partner to help bring this cutting-edge technology to market," he continued.

This news is preceded by Canary Medical's recent FDA clearance of the Canturio Smart Extension (canturio®*se*), a 30mm version of the smart tibial stem extension integrated with Zimmer Biomet's Persona IQ® - The Smart Knee® for patients whose physician believes would benefit from a shorter tibial stem. The canturio®*se* will broadly be commercially available later in 2024. The current 58-mm canturio®*te* stem is still available for patients requiring a longer tibial stem.

About Canary Medical
Canary Medical is a medical data company focused on the development and commercialization of its patented implantable sensor technology and complementary data and analytics ecosystem. In 2021, Canary Medical introduced canturio®*te*, the world's first "smart knee" tibial extension, which is implanted in the body where it monitors patient activity and joint performance, and transmits data to the cloud, autonomously, requiring almost no patient compliance or physician involvement. The Company was conceived and created with the vision that healthcare transformation requires reliable and cost-effective healthcare data and that the effective monitoring and analysis of that data will produce better outcomes for patients at lower costs. Canary Medical is led by a team of experienced entrepreneurs, researchers and data scientists globally regarded for their expertise in medical device design, development and data informatics.

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Canary® Quantiles® software and services, and Canary® Recovery Curves® analytics provides health care professionals (HCPs) with additional aggregate population data when managing a patient's total knee arthroplasty (TKA) post-surgical care. HCPs can filter or select options for additional views based on patient demographics (e.g. age), to analyze trends and outcomes. Canary Quantiles software and Canary Recovery Curves analytics allows HCPs to view aggregate patient population data to analyze patient recovery progress and direction of outcome.

Canary® Quantiles® software and services, and Canary® Recovery Curves® analytics does not control the function or parameters of the Canturio® Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System and is not intended for active patient monitoring.

The canturio®*se* (Canturio® Smart Extension or CSE) with Canary Health Implanted Reporting Processor (CHIRP®) System is intended to provide objective kinematic data from the implanted medical device during a patient's total knee arthroplasty (TKA) post-surgical care. The kinematic data are an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery.

The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 30mm sized tibial stem extension.

The objective kinematic data generated by the CSE with CHIRP System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit.

The CSE with CHIRP System is compatible with Zimmer Biomet's Persona® The Personalized Knee® System.

Canturio® Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System is intended to provide objective kinematic data from the implanted medical device during a patient's total knee arthroplasty (TKA) post-surgical care. The kinematic data are an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery.

The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58mm sized tibial stem extension.

The objective kinematic data generated by the CTE with CHIRP System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit.

The CTE with CHIRP System is compatible with Zimmer Biomet's Persona® The Personalized Knee® System.

Warning: The kinematic data obtained from this device have not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision making, and not data have been evaluated by FDA regarding clinical benefits.

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