



DentalMonitoring Sets New Standard In Orthodontic Remote Monitoring With De Novo Approval By the U.S. Food and Drug Administration (FDA).

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PARIS--(BUSINESS WIRE)--*DentalMonitoring*®, the leader in AI-powered remote monitoring for orthodontic treatment, has received De Novo approval from the U.S. Food and Drug Administration (FDA) for the *DentalMonitoring* solution to be used by orthodontists in optimizing clinical care.

DentalMonitoring is a medical device software using image processing algorithms to analyze pictures of the oral cavity (hereinafter Scans). Scans are taken using the DM App, a smartphone, and the manufacturer's proprietary hardware products.

DentalMonitoring is indicated for use for patients over the age of 6 and reports results solely on permanent teeth.

The product is designed to assist healthcare professionals in remotely monitoring dental treatments, orthodontic treatments, oral health, and treatment progress. The results of *DentalMonitoring* are intended to be used as an aid in diagnosis and not on a stand-alone basis for clinical decision-making.

DentalMonitoring provides additional information compared to traditional orthodontic treatment follow-up. *DentalMonitoring* is an additional asset to ensure patient compliance to orthodontic treatment requirements. With *DentalMonitoring*, clinicians enjoy an elevated level of insight into treatment progress while patients enjoy increased convenience. Automated notifications and in-app communication with practice staff increase patient accountability and enhance communication between patients, healthcare providers, and caregivers.

With this approval, DentalMonitoring will also introduce the innovative SmartSTL™ feature to North American orthodontist customers. *SmartSTL* allows doctors to request updated STL files via the *DentalMonitoring* dashboard without bringing the patient back into the office.

"We are proud to be the new standard of care in orthodontics. This is a recognition of our 10 years of research and development in Deep Learning Artificial Intelligence. FDA approval of this improved version of *DentalMonitoring* software is a key milestone for *DentalMonitoring* and marks the beginning of a new era in orthodontics," says Philippe Salah, CEO and co-founder of *DentalMonitoring*.

Since 2012, only four De Novos have been granted by the FDA Dental panel, and none were software-based devices. *DentalMonitoring* is the first Artificial Intelligence/Machine Learning-enabled Software as a Medical Device in dentistry, establishing a classification within FDA dental regulation numbers and product codes. With the grant of this De Novo and the creation of a new regulatory category, *DentalMonitoring* has paved the way for future innovations in the Software as a Medical Device in the dental field category.

This clearance is a result of Dental Monitoring's investment in pushing digital health technologies to the forefront of dental care. *DentalMonitoring*'s innovation has benefited users with elevated clinical outcomes and increased their peace of mind.

About *DentalMonitoring*:

DentalMonitoring is transforming orthodontic care globally through our advanced AI-driven platform. Our mission is to empower orthodontic practitioners with precise, real-time treatment monitoring and decision-making tools. By enhancing the connection between clinicians and patients, we make it possible to optimize treatment outcomes and ensure high-quality, efficient, and personalized orthodontic experiences.

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