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Isohelix Files US FDA 510k Pre-Submission for GeneFix® Saliva DNA Collectors

Isohelix (UK), the specialist biological sample collection company, announces that it has commenced engagement with the U.S. Food and Drug Administration (“FDA”) to progress the full regulatory approval of the **GeneFix®** Saliva DNA Collectors into the USA.

The **GeneFix®** Saliva DNA/RNA Collection devices are market leading and designed for the collection and preservation of DNA/RNA from saliva, providing patients with the opportunity to provide high-quality samples for molecular diagnostics at both point of care settings and for over the counter direct to consumer genetic testing (OTC).

Isohelix has submitted via the FDA’s Pre-Submission process (“Pre-Sub”), which allows the company to clarify its testing and validation approach, confirm the appropriate regulatory application pathway (510k) and gain additional procedural feedback from the FDA with the aim of making the final submission process more efficient.

Since 2013, **Isohelix** has been successfully supplying its range of high-quality DNA and RNA saliva collectors and isolation products to the Diagnostics, Clinical and Research markets, with many products already certified for use as IVD’s across the globe. **Isohelix** is an international business marketing its sizeable product range through customers in many countries worldwide.

Tom Hole, CEO of Isohelix, said: “The US is a particularly attractive territory and the 510 (K) would allow us to supply our products into the rapidly expanding areas of Molecular and Precision Genetic Diagnosis and Testing, where saliva has become a strong choice as an alternative to blood or the use of buccal swabs. **Isohelix** provides saliva collectors that are proven to cope with the most demanding downstream processes, yet are easy to use for automated applications, non-hazardous and reliably stabilize both DNA and RNA over extended periods at room temperature.

About Isohelix (www.isohelex.com)

Isohelix is a division of the UK based Life Sciences manufacturing company, Cell Projects Ltd. **Isohelix** develops and manufactures high quality DNA/RNA products designed to make the collection, stabilization, and isolation of samples simpler, easier to use and more accessible to the market. The company also produces solutions for buccal cell samples such as buccal swabs and stabilization buffers for use in genetic analysis.

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