

FDA Engagement Commences for Saliva Glucose Biosensor in the US

2020-05-06

The iQ Group Global is pleased to announce that Life Science Biosensor Diagnostics Pty Ltd (LSBD) has commenced engagement with the US Food and Drug Administration (FDA) for the approval pathway of the Saliva Glucose Biosensor.

On May 1st, LSBD lodged a 513(g) submission, the first step to seeking regulatory approval for a device with the FDA.

Within 60 days from submission date, it is expected that the FDA will provide feedback regarding their assessment and the applicable regulatory pathway to this novel device, which will inform further submission proceedings.

The first innovation to be developed from the **Biosensor Platform**, the Saliva Glucose Biosensor is currently being developed by LSBD as a point-of-care test intended to replace finger-prick blood glucose testing for monitoring diabetes.

“This is a key milestone for The Group, as this engagement with the FDA will facilitate our next steps in launching the Saliva Glucose Biosensor in the North America region and, pending further regulatory submissions, the Asia Pacific, so that we can bring this technology to those who need it most – people living with diabetes,” Group Chief Executive Officer Dr. George Syrmalis said.

“As we move through an unprecedented period of pressure for global governments, healthcare services and economies, innovation in life sciences has never been more urgent, nor more important,” Dr Syrmalis said.

“During the COVID-19 pandemic, The iQ Group Global remains relentlessly committed to developing essential

innovations in healthcare that meet unmet clinical needs on a global scale.”

About The iQ Group Global

The iQ Group Global is a group of companies that finds, funds and develops bioscience discoveries to create life-changing medical innovations. The Group’s flagship innovation is the Saliva Glucose Biosensor, in development as the first non-invasive replacement for finger-prick blood glucose testing for people living with diabetes. Read more: **[The iQ Group Global](#)**