THE DIAGNOSTIC PACIFIER

EXECUTIVE SUMMARY

Far too often, predictive factors for disease go unnoticed in developing children, which can lead to debilitating and long lasting effects. These adverse effects impact the cost of health care later in life but more importantly could have a negative effect on their quality of life. We have the ability, at this critical life stage, to implement an easy-to-use at home monitoring system that health care providers could use to identify disease risk factors in their patients and prescribe early treatments. This form of proactive intervention can not only drastically reduce the cost and complexity of treatment but also importantly increase the effectiveness.

PROBLEM AND CLINICAL NEED

Symptoms of cognitive impairment detected early in a child’s development are most likely indicative signs of intellectual disability

MARKET

With our product intended for infants below the age of 24 months, the person purchasing our diagnostic pacifier would be a concerned caregiver. We also expect referrals from pediatricians who are concerned about delay in their patient’s motor, learning, cognitive, social, or emotional development. About 92 million children in the United States ages 3-17 have developmental disabilities including intellectual disability, emotional/behavioral disorder, autism, ADHD, stuttering or stammering, hearing loss, blindness, and other learning disabilities (1). 3.5 million children ages 4-17 have parents who have told a health professional about an emotional or behavioral difficulty (2). Considering that children with developmental disabilities often present with a comorbid mood disorder, the potential market can be estimated to be somewhat less than the sum of these two populations.

NOVELTY OF THE DESIGN

The proposed product is a novel integration of a saliva collection system within a pacifier device. Current saliva methods are often cumbersome and uncomfortable for infants. Many existing collection techniques require the patient to chew on or hold a sponge in their mouth to absorb saliva, which is then extracted from the sponge. This is unusable for infants due to the risk of ingesting and choking. Some of these methods have also been shown to reduce the levels of biomarkers present in collected saliva over a passive “dripping” technique. This method requires patients to passively drip into a test tube, but infants are incapable of performing this action for themselves. Our device draws upon the analytically beneficial technique of passive “dripping” and collects saliva without any inconvenience or discomfort to infant or caregiver. In a search for prior art, many devices integrate a medical functionality into a pacifier device. These functionalities cover a broad spectrum of use, including dispensing medication, monitoring feeding, and measuring body temperature. No device, however, combines the pacifier device with saliva collection. We would anticipate our future competition to be other pacifier devices or infant toys that would incorporate a different method of saliva collection.

The purpose of this design is to enable doctors and parents to noninvasively collect biomarkers for early detection of cognitive impairment. To accomplish this our design employs saliva as the biological sample because it allows for the detection of melatonin and cortisol. We have determined the system for our design will consist of four components. These components will work together to periodically collect saliva samples with little user input, which can then be processed by the doctors who have prescribed this device.

COST

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<th>Device</th>
<th>Description</th>
<th>Price (USD)</th>
<th>Quantity</th>
<th>Subtotal (USD)</th>
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TOTAL: $8.08

REGULATORY PATHWAY

Our device would be considered Class II device by the FDA and would require the submission of an FDA 510(k). This means that our device is similar to already approved products, and would require the submission of an FDA 510(k). This means that our device is similar to already approved products. Other pacifier devices, such as digital pacifier thermometers, have also completed this process.

ACKNOWLEDGMENTS

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REFERENCES