Right Under Your Nose: A Novel Smell Training Device

Design Team 6

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Project Summary

Olfactory Dysfunction (OD) is a condition which disrupts the ability to perceive and distinguish between smells and is shown to be comorbid with a variety of other conditions, especially cognitive disorders like Parkinson's and Alzheimer's and psychiatric deficits such as depression. Identification of OD can be a vital data point in the differential diagnosis and potential early recognition of many neurodegenerative diseases in eldery patients; thus, there is merit in determining whether a patient has OD, whether or not they are aware that they have it. The current standard of care involves measuring and benchmarking the extent of a patient's smelling capabilities using a smell test. The most standard testing protocol involves the use of an paper booklet "scratch-n-sniff" test which is administered by an ENT specialist at the clinic. However, this means many patients who have unrecognized OD will not be smell-tested as it's difficult to obtain accurate at-home test results using these products since many factors such as smell-intensity and distance from the nose are variable. Additionally, patients with certain forms of OD can regain their olfactory acuity via smell training (i.e., patients who have suffered a viral infection). Smell-training involves patients smelling sequential scents while viewing visual cues and can improve a patient's olfactory ability by taking advantage of neuroplasticity. There is currently no gold standard olfactory training kit to which physicians can refer their patients while existing kits are rudimentary, consistig of jars of essential oils. Thus, physicians need a consolidated at-home method for screening and training olfactory function across their patients in order to aid in the differential diagnosis of conditions in which olfactory dysfunction is a symptom. We hope to meet this need by developing a device along with a companion mobile application which is able to guide patients through the process of smell-testing as well as offer smell-training regimens. Patients' screening results and training progress can be recorded in app.

Questions

1. The FDA 510k submission requires listing of medical device precedents. How extensive should this list of precedents be? Our device is loosely based on the existing UPenn Smell Identification test which is a paper booklet. Do all

mechanism within our device (i.e., rotating components, essential oils, etc.) need to have their own medical precendent?

2. How will having a digital component (mobile application) affect our navigation of the 510k pathway?