

White Paper Reviews

Order of presentation:

1) Improving Early Detection of Cancer of the Oral Cavity – A Breakthrough in Technology

The foundation of our value proposition. The summary and data submitted to FDA that earned Breakthrough Designation.

- Summary:
 - 5 Year Survival Rates aren't much better than a coin flip
 - Nearly 73% of cases are diagnosed at Stage 3 or Stage 4
 - Early detection will save lives
 - Product Description:
 - Pre-diagnostic, point of care oral cancer risk assessment test
 - Uses a small sample of patients saliva, a lateral flow test cassette and Reader to provide an accurate Risk Assessment that provides objective information to more accurately determine when to escalate care
 - Combines Biomarker concentration algorithm / Sensor Fusion Algorithm / CRF algorithm to provide an overall Sensor Fusion algorithm to produces Risk Assessment
 - Study Design:
 - Case-controlled Study performed with samples taken from European and U.S. sites, confirmed pathology of – samples sent to laboratory for testing, samples also tested using OraFusion System
 - CRF developed from cohort of over 480 oral cancer cases
 - Biomarker Sensor Fusion created from a subset of over 940 saliva samples to provide statistical significance
 - Reviews the current workflow vs recommended workflow
 - Reviews the Clinical Results and significant impact of Overall OraFusion System Function
 - That caused FDA to grant Breakthrough Designation

2) Advancing Oral Cancer Detection – An In-Depth Analysis of BeVigilant OraFusion System

- Summary:
 - Reviews Survival Rates and need for Early Detection
 - Reviews the BeVigilant OraFusion System
 - Early Stage Biomarkers (early-stage is key)
 - Clinical Risk Factors
 - How they work together as Sensor Fusion
 - Summary of Accuracy
- “Where Providers once faced uncertainty, now they have much needed clarity and data driven confidence to accelerate detection for improved patient outcomes”*

3) Performance of a Salivary Lateral Flow Point of Care Device as an Aid in the Management of Patients With Oral Cavity Mucosal Abnormalities

- Summary:
 - The white paper that shows 2x improvement in a dentist's ability to know when to escalate care
 - Reviews current state of oral cancer and early detection is key to increasing survival rate
 - Conventional exam is subjective and unnecessary biopsy is invasive and painful
 - Panel of dentists from very busy practices were shown 110 deidentified images of oral cavity lesions with biopsy confirmed oral cancer / high grade dysplasia / Potentially malignant histology / benign.
 - Images were provided from 2 university dental schools with the diagnostic pathology reports
 - Round 1: reviewed just the images and classified based on need to escalate care
 - Round 2: after a wash out period, images were shuffled and classified again
 - And then they were provided the OraFusion test results
 - Review the results chart – significant improvement by using the OraFusion test

4) Original White Paper: Novel Breakthrough OraFusion System for Suspicious Oral Lesion Risk Assessment in the Dental Practice

- This paper takes you through everything about the system development, details and data
- It's very thorough
- Oral cancer impact
- Review of system components
- Current workflow with inclusion of OraFusion System
- Risk Assessment Results
- System Architecture in detail
- Biomarker selection process – matched pair development – testing results – creation of cut-off values – ELISA results for confirmation – concentration cut-offs – biomarker alignment results – CRF algorithm – Sensor Fusion function – complete OraFusion algorithm semi-quantitative output

“it's Complicated”

Very valuable but we need to be able to translate it into the “so what” of selling

P16 is a tumor suppressor Protein and cell cycle inhibitor that is widely used as a surrogate biomarker for HPV infection

EGFR (EFGR / ErbB1 / HER1) overexpression is found in the majority of OSCC tumors and associated with poor prognosis

Key Point: Custom Antibody – Antigen Matched Pairs

Leads to greater accuracy and repeatable, consistent results