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Trimira Debuts *Identafi 3000* Light-Based System For Oral Cancer Detection

Trimira is seeking to position its recently unveiled *Identafi 3000* multi-spectral oral cancer screening system as a user-friendly alternative to existing tests.

About the size of an electric toothbrush, the handheld device received 510(k) clearance in February and recently launched with a list price of \$3,395, according to Trimira, a Houston-based subsidiary of Remicalm.

Trimira is marketing its device through a combination of national and regional distributors as well as 40 contract sales reps.

Identafi uses three wavelengths of light to test for oral cancer, CEO David Burns explained in an interview. According to the firm, the multi-spectral approach leads to fewer false positives and unnecessary follow-up biopsies.

The device first emits white light during a conventional examination, followed by an observation with violet light. Under the violet light, suspicious tissue will appear dark. If abnormalities are present, the technician will switch to a greenish amber light, which can distinguish between normal and abnormal tissue vasculature.

Identafi will compete with products including Zila's *ViziLite Plus* oral lesion identification and marking system and *OraTest* mouthwash, and CDx Laboratories' *OralCDx* brush biopsy tests. About 30,000 cases of oral cancer are diagnosed annually in the U.S., Burns noted, adding that about 7,500 people die of the disease each year, underlying the need for early detection.

Trimira plans to investigate additional indications for Identafi, including esophageal and intestinal cancers. The light-based technology "can be used easily in any mucosal tissue," Burns said.

The firm also is developing a cervical cancer detection system, which will require PMA approval. Burns said the company is hoping to begin clinical trials in April or May. "This will be something which will quickly read [cervical tissue] and tell you whether you've got a problem and then ... you'd have a biopsy taken immediately," he explained.

– Brooke McManus (b.mcmanus@elsevier.com)

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