

ASX Announcements

31 May, 2001

FDA CLEARS OPTISCAN STRATUM FOR US MARKET

Optiscan Imaging Limited is pleased to report that a response has been received from the American Food and Drug Administration (FDA) in relation to the Company's "Stratum" microscope.

As anticipated by the Company, the Stratum falls into regulatory Class 1 and is an exempt medical device. The FDA has found the Stratum to be exempt from the pre market notification requirements of the United States Federal Food, Drug and Cosmetic Act

This means the company may immediately begin marketing in the USA as there are no further regulatory barriers in respect of the current Stratum product.

The company is pleased with this outcome, as the exemption enables immediate market access, and avoidance of the more lengthy and demanding approval processes required for non exempt devices. More importantly, it allows the company to focus its efforts and resources on commercial and strategic initiatives rather than compliance outcomes.

Peter Delaney Managing Director