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FDA CLEARANCE FOR OPTISCAN'S FLEXIBLE ENDO-MICROSCOPE

Optiscan announced today that the US Food and Drug Administration (FDA) has provided regulatory clearance for the Pentax/Optiscan flexible endo-microscope to be sold in the USA.

This follows the announcement on 15 October that regulatory approval for Europe and other countries, known as "CE Mark", has also been granted.

The regulatory clearances now enable Pentax to make final preparations for market release, involving the production of product marketing materials and product specification information, plus arrangements for commissioning of instruments and training programs for operators.

The Flexible Endo-microscope System has been designated as a Class II medical device for regulatory purposes. The FDA's Centre for Devices and Radiological Health gave the regulatory clearance after a 510K application was submitted by Pentax's US subsidiary with supporting technical and clinical trial material provided by Optiscan.

"This is a significant milestone for Optiscan because FDA clearance is a pre-requisite for sales in the USA", said Matthew Barnett, Optiscan's CEO. "Class II regulatory clearance is an important commercial step in the evolution of our products because it allows their use to image cell structures inside the body."

The flexible endo-microscope was jointly developed with Pentax following the establishment of a collaborative development partnership in February 2002. Under that agreement, Pentax will conduct worldwide marketing of the product through their international sales and service infrastructure.

Prior to receiving regulatory clearances, marketing activities conducted by Pentax and Optiscan have generated strong interest in the leading edge technology by focusing on its clinical efficacy. Pre-release activities to date have included:

- Medical journal publications. The endo-microscope featured in "Gastroenterology" with the a rapid communication article reporting the technology's demonstrated clinical efficacy in diagnosing neoplasia (early stage cancers), very favourable editorial coverage and the cover showing images of cellular structures obtained with the technology. "Gastroenterology" is the leading peer reviewed journal in the field of gastrointestinal medicine and provides unprecedented exposure into the target market for the instrument.
- The clinical trial program. Pre-production versions of the instrument have been used at leading teaching hospitals in Australia, Germany, USA, France, Japan and Singapore. These have provided excellent clinical efficacy data.
- Medical Conference Exhibitions. Pentax have exhibited the flexible endo-microscope to potential buyers at more than 11 industry conferences and exhibitions in 8 different countries.

- Live demonstration days. Pentax has also run a series of live demonstrations of endo-microscope procedures to physicians. This has been effective in showcasing the technology and its utility to opinion leading doctors and groups of gastroenterologists.

Optiscan reported earlier this month that it has commenced component sales to Pentax. The Optiscan miniaturised confocal microscope system is integrated with the Pentax endoscope, ready for sale to final users. Pentax is now expected to complete the remaining activities required for market release, including transfer into full production, in the first quarter of 2005.

Further information:

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