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24 September 2003

Safety Scalpel Granted FDA Clearance

Occupational & Medical Innovations Limited (OMI) is pleased to announce that the US Food and Drug Administration (FDA) has given clearance to market its Safety Scalpel throughout the United States of America.

In the United States, medical devices are subject to the general controls of the Federal Food Drug & Cosmetic (FD&C) Act, which are contained in the final procedural regulations in Title 21 Code of Federal Regulations Part 800-1200 (21 CFR Parts 800 - 1299). These controls are the baseline requirements that apply to all medical devices necessary for marketing, proper labelling and monitoring its performance once the device is on the market.

With FDA clearance, OMI's Safety Scalpel will make its commercial debut in the next few weeks. Personna Medical, a division of the American Safety Razor Company will distribute the award winning scalpel throughout the USA, Canada, Mexico & the Caribbean.

OMI's first sales order from Personna Medical is already pre-sold and is ready for distribution.

The scalpel already has approval from the Therapeutic Goods Administration (TGA) in Australia and will be released throughout the Australian market in the next few weeks.

A handwritten signature in dark ink, appearing to read 'B. Kiehne', with a horizontal line extending to the right.

Bruce Kiehne
Managing Director