



The Manager

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Company Announcements  
Australian Stock Exchange  
4<sup>th</sup> Floor  
20 Bridge Street  
SYDNEY NSW 2000

Dear Sir,

## **US approval for FerriScan™ closer with FDA 510(k) submission**

**Perth, Australia, Wednesday 1 December 2004:** Resonance Health Limited (ASX:RHT) today announced the lodgement of a 510(k) submission with the US Food and Drug Administration (FDA) for its novel diagnostic test for liver iron concentration - FerriScan™.

Successful approval of the FDA 510(k) filing will allow Resonance Health subsidiary, Inner Vision Biometrics Pty Ltd (IVB) to market the FerriScan™ test in the United States where an estimated four million people are afflicted with an iron overload disease such as haemochromatosis and thalassaemia.

The 510(k) submission, which is required prior to US launch of a medical device, follows last week's announcement about the successful listing of FerriScan™ by the Australian regulatory authority, the Therapeutic Goods Administration (TGA), and therefore reciprocal access to Europe markets with CE Mark approval.

FerriScan™ is now poised for international roll out through collaborations with leading radiology groups in Australia and the United Kingdom.

"FDA approval is the key regulatory requirement prior to launching FerriScan™ in its largest market and we have already initiated discussions with potential partners in the US to provide the FerriScan™ service. The US has a well developed MRI infrastructure and attractive pricing to underpin commercial success for FerriScan™," said Mr. Tony Fitzgerald, Executive Director of Resonance Health.

"Last week we received confirmation by the TGA that FerriScan™ would be listed in Australia and reciprocal rights with European regulatory authorities through the CE Mark, will allow the test to be offered in Europe also. We will be utilising our existing partnerships with leading diagnostic imaging companies in Australia and Europe to offer the FerriScan™ test to the public."

The Pre-market notification or 510(k) allows the FDA to determine whether a device is equivalent to one that has already been classified. It is generally a much faster process than FDA approval for drugs and once approved the device is able to be sold to the US market.

## **Further information**

### **About Haemochromatosis and Thalassaemia**

Haemochromatosis is a genetic disorder that causes iron deposition in the liver, and in other organs of the body, resulting in iron overload. The condition frequently remains undiagnosed because of lack of awareness, its long latency period and its non-specific symptoms.

Thalassaemia, a genetic blood disorder and a very severe and debilitating form of anaemia, also results in iron overload due to the requirement for frequent blood transfusions.

### **About Resonance Health Ltd**

Resonance Health Limited controls 51% of the voting rights of Inner Vision Biometrics Pty Ltd (IVB) and is earning 51% of the equity of IVB via the progressive injection of further capital. FerriScan™ is 100% owned by IVB.

FerriScan™ is a novel, non-invasive diagnostic test of the iron content of a patient's liver to assist clinicians in the detection and treatment of iron overload disorders such as thalassemia and hereditary haemochromatosis. The FerriScan™ diagnostic test service uses existing MRI (magnetic-resonance imaging) machines at radiology facilities worldwide which can be configured to provide a suitable scan of the liver that is subsequently analysed at the centralised IVB image analysis centre to quantify iron loading using proprietary software. The FerriScan™ test provides a safe alternative to liver biopsy and will become a valuable adjunct to gene testing for iron overload diseases. Liver biopsy is an unpleasant, invasive procedure requiring liver tissue to be extracted from the patient by needle.

Further information concerning Resonance Health and FerriScan™ can be obtained from the following web sites: [www.resonancehealth.com](http://www.resonancehealth.com) [www.ferriscan.com](http://www.ferriscan.com)

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