Resonance Health Ltd
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FDA requests a broader Indication for Use for FerriScan

The Food and Drug Administration (FDA) has requested Resonance Health to submit an expanded Indication for Use for FerriScan to include its specific role in the use of iron chelation therapy. Following this change, FerriScan would be considered to be a companion diagnostic device which provides information that is considered essential for the safe and effective use of a corresponding therapeutic product. The use of a companion diagnostic device is stipulated in the Instructions for Use of both the diagnostic device (FerriScan) and the corresponding therapeutic product.

The approved Indication for Use of a medical device provides the scope for marketing and product claims and labelling. FerriScan is currently indicated for the measurement of liver iron concentration. Expanding the FerriScan Indication for Use is an acknowledgement of the important role FerriScan plays in clinical trials and in the clinical use of iron chelation therapies.

This change has important potential implications for FerriScan and may:

- Assist with gaining reimbursement for FerriScan in the US.
- Lead to a broader use of FerriScan following this acknowledgment of its important role in the management of patients with iron overload.
- Require any new competing medical device products seeking FDA approval to provide evidence to support claims of equivalence to all the FerriScan Indications for Use.

Iron chelation therapy is currently used for patients with iron overload that results from receiving regular blood transfusions and clinical trials are currently exploring its use in patients with non-transfusion dependent iron overload. Estimates of the number of people in the US who receive regular blood transfusions and require an annual assessment of their iron overload to effectively manage their therapy range from 15,000 and 25,000. The number of patients with non-transfusion dependent iron overload is estimated to be significantly above this.

Resonance Health currently provides FerriScan to 40 MRI facilities in the US. Approximately 1,000 FerriScans were provided to the US in the last 12 months and we are hopeful that FerriScan usage will increase following these changes. Resonance Health is currently working with the FDA to process this change to the Indication for Use of FerriScan.

By Order of the Board
Resonance Health Limited

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Resonance Health Ltd (ASX: RHT) (www.resonancehealth.com) is a medical device company providing imaging core laboratory services for the quantitative analysis of medical images, with a subspecialty in the liver. Resonance Health's patented FerriScan technology provides a safe and accurate alternative for measuring liver iron concentration, and research continues into the development of new technology for the accurate assessment of liver fat and liver fibrosis.