

Mac Dalton

By email: fyi-request-11744-2a2c8d00@requests.fyi.org.nz
Ref: H201910165

Dear Mr Dalton

Response to request for official information

Thank you for your request of 26 November 2019 to the Ministry of Health (the Ministry) under the Official Information Act 1982 (the Act):

"In other jurisdictions the Apple Watch (Series 4 and 5) has been approved for use to produce ECGs.

I am curious as to whether this approval process is underway in New Zealand. As such, I'm seeking any relevant information you can provide me relating to this. For example, I'm interested in any applications, responses to applications or correspondence related to any applications."

Medsafe does not receive or process applications for approval as there is no approval or registration of medical devices in New Zealand. For this reason your request is refused pursuant to section 18(e) of the Act, as the information requested does not exist.

There is a mandatory requirement that the New Zealand sponsor (ie. the importer, distributor or local manufacturer) of a medical device notifies their device to a Medsafe notification database. Notification to this database does not mean or imply that a medical device has been assessed by Medsafe in terms of quality, safety, efficacy or performance.

Under the Act, you have the right to ask the Ombudsman to review any decisions made in this response.

Please note that this response, with your personal details removed, may be published on the Ministry website.

Yours sincerely



Nick Allan
Manager OIA Services
Office of the Director-General

