MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T +64 4 496 2000
W www.medsafe.govt.nz

20 May 2024

s 9(2)(a)

[redacted] [redacted]
Ref: H2024040123

Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) which was transferred from the Ministry of Foreign Affairs and Trade - Manatū Aorere to the Ministry of Health – Manatū Hauora (the Ministry) on 23 April 2024 for information regarding the importation of surgical mesh products. You requested:

> *"…What evidence, if any, was provided by the manufacturers to prove their products were safe, particularly their safety following several years of insertion in the human body."*

There is currently no legislative provision for medical devices to be assessed and approved prior to marketing in New Zealand. Your request for this evidence is therefore refused under section 18(e) of the Act, as the information does not exist.

There is a legislative provision in section 38 of the Medicines Act 1981 for Medsafe to place restrictions on the sale of a medical device if it is thought to be unsafe. This provision was used by Medsafe in 2017 in relation to a number of surgical mesh devices supplied in New Zealand. Actions taken by Medsafe in relation to surgical mesh are published on the Medsafe website at www.medsafe.govt.nz/devices/Surgical%20Mesh/ActionsTakenByMedsafe.asp.

If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: oiagr@health.govt.nz.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Chris James
Group Manager
Medsafe