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FDA nod opens US market to G Medical

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ASX-listed e-health provider G Medical has received US Food and Drug Administration approval for its Prizma medical smartphone jacket, paving the way for US commercialisation.

The Prizma is a smartphone product which turns a consumer's phone into a mobile medical monitor, measuring vital signs and performing diagnostics. It connects to an app which stores that data in the cloud, and presents a health profile by continuously collecting and analysing medical data, detecting trends over time.

G Medical chief executive Yacov Geva told *The Australian* the FDA approval came much sooner than he was expecting. Similar regulatory approval applications were in progress in China, Europe and Australia.

"FDA approval is a major milestone for G Medical as it paves the way to confidently move forward with our Prizma launch and commercialisation plans," he said. "The FDA approval is a clear vindication of G Medical's vision and future product pipeline and development, sending positive signals to other markets around the world."

The news follows a binding memorandum of understanding G Medical signed for \$US67.5 million (\$84m) for China distribution in July with Shandong company Boletong. Agreed terms in that deal include a minimum purchase order of the Prizma smartphone jackets, as medical support via nurse and physician-staffed call centres.

Dr Geva said he was looking to ink similar deals with other companies in China, given Bole-

tong cannot cover China itself.

"We're also in discussions with companies that have developed IT software for hospitals, and partner with them by selling our services and products into those hospitals," he said.

The CEO, who has been running public companies for more than two decades, said once the regulatory hurdles were complete, the potential market for G Medical's devices was huge. He said now the FDA had approved Prizma it would be available in the "near future".

"I take a philosophical approach to it," Dr Geva said. "Why wouldn't we take every smartphone available today, and convert it into a medical device? It's putting a doctor in your pocket. It protects your phone firstly but also protects, in a way, your life."

"The Prizma has a variety of sensors with things you can measure yourself, like ECG, temperature, stress levels, heart rate. In 2018 you will see more and more sensors into this device."

The company listed on the ASX in May, following a \$12m IPO raising that gave it a market capitalisation of \$45m.

Shares in G Medical closed down 12.4 per cent at 39c.