

Tegenix FDA Review Progress

6 October 2026

Bone Regeneration Franchise

Tetratherix Limited (ASX: TTX) advises that it has received a substantive review update from the US Food and Drug Administration (FDA) on its 510(k) submission for Tegenix.

The FDA's review has confirmed the core elements of the submission, including device classification, the nominated predicate device and the performance testing data. The FDA has requested extra detail on basic chemical characterisation and final product labelling which is mostly administrative.

This level of initial enquiries was expected considering the Tetramatrix™ platform polymer is entering the pathway as a novel material. TTX and its partners are actively compiling the information on hand for expedited submission. TTX regards this update as a material validation of both the submission and the Tetramatrix™ platform.

TTX will keep the market informed as the FDA review advances toward the final clearance decision.

Will Knox, CEO, said:

"The FDA has examined the foundations of the Tegenix submission. Importantly there were no questions raised on the classification, the predicate and the performance data. Those elements carry the substance of any 510(k), and for a new material they carry the most risk. The Tetramatrix™ platform polymer is being reviewed for the first time by the FDA, its questions on chemical characterisation and labelling are the questions a careful regulator asks of something innovative. Our task now is to deliver our response with the same rigour and speed that brought the submissions this far. The timing of a clearance decision will rest with the FDA, and we look forward to reporting it to the market when it comes."

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Authorised for release by the CEO.

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