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ASIA EDITION

South Korea's STARMED secures US FDA clearance for thyroid nodule ablation

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STARMED is the first company, and currently the only one, with an FDA indication for RFA of thyroid nodules in the US



STARMED, a South Korea-based medical device company specialising in minimally invasive treatment technologies, has announced that it has obtained 510(k) clearance from the US Food and Drug Administration (FDA) for a thyroid-specific indication. The company's system may now be used for ultrasound-guided percutaneous ablation of eligible, cytologically confirmed benign thyroid nodules in adults.

STARMED is the first and only company in the world to have obtained an FDA clearance for an indication specific to thyroid nodule ablation.

The specificity of the labelling clearly distinguishes the clearance from a general soft-tissue ablation indication. The clearance directly names thyroid nodules, ultrasound guidance, the percutaneous approach, the adult patient population, and the applicable clinical eligibility criteria.

The cleared STAR RF Electrode is a radiofrequency (RF) ablation electrode engineered to support precision in ultrasound-guided percutaneous ablation of eligible benign thyroid nodules in adults. The VIVA RF Electrode, also covered by the clearance, is a monopolar electrode with an adjustable active tip that allows clinicians to adjust the ablation size according to clinical need.

STARMED developed the world's first hyroid-dedicated RFA electrode in 2009 and has continued to collaborate with clinicians and academic centres to support technology development, procedural education, and technique refinement. The company currently supports thyroid RFA training centres in more than ten countries, and its thyroid technologies are referenced in more than 300 peer-reviewed clinical publications.