

**Recommendations of the SEC (Radio-Diagnostic) made in its 01<sup>st</sup>/24 meeting held on 21.06.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Medical Device Division</b>			
1.	IMP/MD/2023/61076  Gold fiducial marker (Brand name: Gold Anchor)	M/s. Saxsons International Private limited	<p>Firm presented the proposal before the committee for grant of permission to import and market of medical device i.e. Gold fiducial marker manufactured by, M/s. Naslund Medical AB, Sweden.</p> <p>The firm has informed the committee that the applied device is approved for marketing in various countries like USA, Australia, Japan, etc and used in the population from last more than 10 years. The firm also presented the clinical investigation study data generated on the global population as well as the Post Market Surveillance data of the product marketed till the year 2023.</p> <p>After detailed deliberation and based on the data produced by the applicant, the expert committee opined that the proposal may be considered and recommended that the firm should conduct Post Marketing clinical Investigation to generate safety and effectiveness data of the device on the Indian population.</p> <p>Accordingly, the study protocol should be submitted to Central Licensing Authority, within a period of six months from the date of launch of said device in the Indian market.</p>