

Attachment 4 - Literature Search Methodology

The literature review conducted for this reclassification petition resulted in the identification of 56 articles. The following methodology was applied to obtain these articles:

1. Twelve journal articles were selected by the petitioner, based upon their relevance to the therapeutic applications of capacitive coupling or pulsed electromagnetic field bone growth stimulators.
2. A search of the PubMed database was conducted using key words obtained from the initial 12 articles. The following combinations of keywords were used in this search:
 - Adverse Event
 - Adverse Events
 - Bone Graft
 - Bone Graft Stimulator
 - Bone Growth
 - Bone Growth Stimulator
 - Capacitive Coupling
 - Capacitively Coupled
 - Clinical
 - Electrical Stimulation
 - Fusion
 - PEMF
 - Pulsed Electromagnetic Field
 - Pulsed Electromagnetic Fields
 - Safety
 - Stimulation
 - Study
 - Studies
 - Trial
 - Trials
3. Searches were conducted for the time period ranging from 1950 through mid-2004. A total of 2,289 non-duplicated citations were identified from the search and all 12 initial articles were located among these.
4. Using ProCite and EndNote 7 bibliographic citation programs, the following Boolean filters were applied to limit the search:
 - Title = “combined magnetic AND Title= “spine”
 - OR (Title = “lumbar fusion” AND Title = “nonsurgical”
 - OR (Title = “capacitive coupl*”, “capacitively coupl*”, “pulsing electromagnetic*”, “pulsed electromagnetic”)
5. The above filters resulted in the identification of 166 of the original 2,289 articles, and each abstract was reviewed for relevance to include in the petition.

6. Of these 166 articles, 58 were selected for in-depth analysis, and 42 of those articles were determined to be applicable to the effectiveness discussion within this petition.
7. In addition to the 42 articles, the petitioner conducted a separate search of the literature used in support of marketing applications for the Non-invasive Bone Growth Stimulators currently in commercial distribution in the United States. This search included a review of available and appropriate Summaries of Safety and Effectiveness (SSEs), labeling provided for legally marketed devices at the time of their approval, and other sources.
8. Fourteen articles were identified that were used in support of marketing applications for those devices and had not appeared in the previous literature search. Justification for the lack of identifying the 14 articles during the initial comprehensive literature search is provided in Section VII of the petition.