clinical" OR "initial human" OR "preliminary clinical" OR "preliminary experience" OR "preliminary human" OR "Phase 1" OR "Phase I"). We selected this search term owing to efficiency and being able to identify the most relevant studies. The search was carried out between 1 January 2000 and 31 December 2004 to allow time for regulatory approval, as previous studies have suggested a long lag between the development of a device and subsequent regulatory approval.[7 8]

We included articles that reported a clinical study of a new medical device and excluded those that only reported a laboratory study of a device, because few such devices ultimately result in a clinical study.[9] We also excluded articles if they reported on the novel use of an existing device, as we expected that most such devices would already have received regulatory approval.

Based on a pilot study, we estimated (between 1 January 2000 and 31 July 2000) that this search strategy would select sufficient articles to allow for meaningful analysis.

Two researchers initially screened titles and abstracts to identify relevant articles (HJM and CJP, checked by AHH and APM). We excluded articles if the title or abstract explicitly stated that the article was not original research, related to drug development, related to an existing medical device, or a laboratory study. Full articles were subsequently obtained and further assessed for eligibility. In each instance we reviewed the reference list and searched the PubMed database using the device name to ensure that we did not miss a related previous clinical study (that would result in their exclusion). Discrepancies were resolved by consensus.

Medical devices

For each clinical study of a new medical device, we determined the type of device, the target specialty, and the involvement of academia and of industry (HJM and CJP, checked by AHH and APM). The types of device were based on the FDA definition, and the target specialties were drawn from the FDA databases. We considered academia and industry to be involved in the development of a device if a relevant author affiliation, financial support, or provision of technology was described in the author affiliations, main text, or acknowledgments of the article. Discrepancies were resolved by consensus.

Regulatory approvals

For each new medical device, we searched the FDA databases for a relevant regulatory clearance or approval. The FDA recognises several types of regulatory pathway depending on the nature of the device. Premarket notification (510(k)) is the regulatory pathway if the device is "substantially equivalent" to a predicate device and does not necessarily require clinical data. Premarket approval is the regulatory pathway if the device is "not substantially equivalent," and requires reasonable evidence of safety and effectiveness. Other regulatory pathways include humanitarian device exemption if the device is for use in patients with rare diseases or conditions. We searched the FDA 510(k), premarket approval, and humanitarian device exemption databases using the device name, applicant name, and relevant keywords (HJM and CJP, checked by AHH and APM). We also searched Google for devices that may have been discontinued, withdrawn, or recalled. Search results were not limited to a date range, allowing for the identification of regulatory clearance or approval before the first published clinical study. All the searches were performed in August 2015, allowing a minimum of 10 years from publication to regulatory clearance or approval. Discrepancies were resolved by consensus.

Statistical analysis

To compare differences in regulatory clearance or approval between the following groups we used the χ^2 test: devices developed by industry alone versus academia alone; devices developed by both industry and academia versus academia alone; and devices developed by both industry and academia versus industry alone. Firstly, we compared the proportion of devices receiving any regulatory clearance or approval (versus no clearance or approval). Secondly, we compared the proportion of devices receiving 510(k) clearance (versus any other approval). We considered differences to be statistically significant if P was less than 0.05. All statistical analyses were performed using SPSS 22.0 (IBM, NY, USA).

Patient involvement

No patients were involved in setting the research question or the outcome measures, nor were they involved in developing plans for design or implementation of the study. No patients were asked to advise on interpretation or writing up of results. There are no plans to disseminate the results of the research to study participants or the relevant patient community.

Results

Search strategy

In all, 5574 titles and abstracts were screened, 493 full text articles assessed for eligibility, and 218 clinical studies of new medical devices included (fig 1).

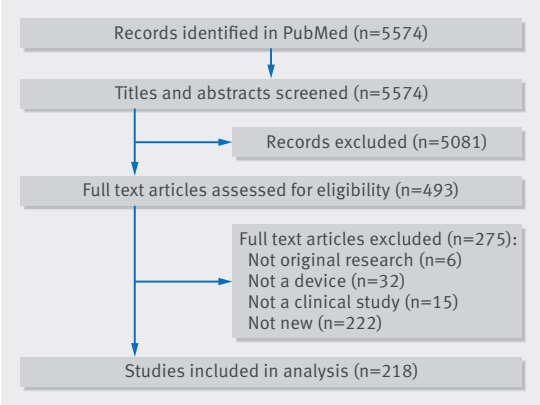

Fig 1 | Flowchart showing selection of clinical studies of new medical devices