Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD  20852


Dear Sir or Madam:

The Advanced Medical Technology Association (“AdvaMed”) is pleased to provide comments on the Food and Drug Administration’s (FDA’s) draft guidance entitled “Spinal Plating Systems—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff.”

The Advanced Medical Technology Association (AdvaMed) is the world’s largest trade association representing medical device and diagnostics manufacturers. AdvaMed’s member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

AdvaMed supports FDA’s efforts to provide safety and performance guidance for specific products. Our general and specific comments (in the attached table) are included below.

General Comments

On the whole, the scope of the draft FDA guidance “Spinal Plating Systems—Performance Criteria for Safety and Performance Based Pathway” is too narrow to be of significant value to companies focused on innovation. For example, lines 108-122 identify as non-eligible, many of the positive improvements spinal plating system manufacturers are targeting to increase device performance and improve patient
outcomes. While this document and pathway could be valuable for a new player in the spinal plating system market, it would likely only be utilized by companies that don’t already have a basic system cleared by FDA. To validate this assumption, it may be of value for FDA to look at all of the spinal plating systems (procode KWQ) cleared in the last 5 years and assess what percent would fall within the scope of this document. Given the energy necessary to create each “Performance Criteria for Safety and Performance Based Pathway” document, resources may be better focused on products that FDA is actively reviewing in high volumes.

Many plate submissions are submitted as bundled submissions. We request that FDA provide clarity on whether it is still possible to bundle devices that fall under this guidance. For example, is it still possible to bundle a thoracolumbar plate submission with different types of plates, where all plates but the buttress plate would qualify for the Safety & Performance Based Pathway? Further, would inclusion of a buttress plate within the submission disqualify the entire submission from the Safety and Performance-Based Pathway or can FDA perform the assessment on a product-by-product basis within the submission? Given the current numbers of bundled submissions, clarification of these issues would be very helpful.

**Specific Comments**
AdvaMed’s specific comments are included below in tabular form.

Please don’t hesitate to contact me if I can help answer any questions.

Sincerely,

/s/

Tara Federici
Vice President
Technology and Regulatory Affairs
<table>
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<tr>
<th>Edit #</th>
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<tbody>
<tr>
<td>1</td>
<td>Line 102, Table 1</td>
<td>Specify whether occipital plates fall under this guidance document. If not, please list in exclusion criteria (lines 108-122).</td>
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<td>2</td>
<td>Line 102, Table 1, Cervical Plates, “Plate Thickness/Profile”</td>
<td>The guidance specifies a maximum plate thickness/profile limit of 3 mm. To ensure continued innovation, it is important to encourage development of lower profile devices (i.e., thinner devices). FDA should clarify if there is a minimum thickness/profile limit for plates beyond which the safety and performance pathway would not be applicable.</td>
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<td>3</td>
<td>Line 102, Table 1, Thoracolumbar Plates, “Plate Thickness/Profile”</td>
<td>The guidance specifies a maximum plate. The guidance specifies a thickness/profile limit of 7 mm. To ensure continued innovation, it is important to encourage development of lower profile devices (i.e., thinner devices). FDA should clarify if there is a minimum thickness/profile limit for plates beyond which the safety and performance pathway would not be applicable.</td>
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<td>4</td>
<td>Line 270 through 305, “Biocompatibility Evaluation” section</td>
<td>Please clarify whether a predicate still needs to be identified if a full battery of biocompatibility testing is conducted on the product and all the recommended biocompatibility endpoints are evaluated.</td>
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Need additional clarification on out of scope products.

Because this is the safety and performance pathway, we believe identification of a predicate material should not be necessary if the full battery of biocompatibility testing is completed.