

1 this design type has no permanent connection between  
2 the components and relies on the soft tissue  
3 structures to hold the components in place.

4 In addition, it's not clear if the  
5 suggested anterior/posterior, medial/lateral, shear,  
6 and/or static tensile pulloff testing will  
7 characterize the clinical propensity for tipping. So,  
8 once again, the value of such testing appears to be  
9 questionable for some designs.

10 Spinout of a tibial insert or patella  
11 bearing has been identified as another risk that is  
12 unique to the mobile bearing knees. Within the  
13 petition, spinout is defined as the excessive rotation  
14 of the polyethylene insert resulting from at least one  
15 femoral condyle riding up and over the lip of the  
16 insert, such that the femoral condyle is no longer in  
17 contact with the insert's articular surface. This can  
18 lead to dislocation, subluxation, wear, impingement,  
19 and instability.

20 To mitigate the risk for bearing spinout,  
21 mobile bearing devices should be evaluated to limit or  
22 eliminate the potential for spinout. Currently, there

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1 is no standard for spinout testing. However, the  
2 sponsor has suggested that the potential for tibula  
3 insert spinout may be assessed using a modified knee  
4 constraint testing standard after adapting for  
5 physiologic compressive loads, rotary torques, and  
6 various moments that are deemed to be causative of  
7 insert spinout.

8 This ASTM standard, which is a standard  
9 test method for the determination of total knee  
10 replacement constraint, is one of the same special  
11 controls used for the evaluation of fixed bearing  
12 knees. To evaluate the risk of the patella bearing,  
13 they suggest a patella/femoral lateral stability test,  
14 as recommended in the current fixed bearing knee  
15 guidance.

16 The sponsor believes this testing should  
17 provide reasonable assurance that the insert bearing  
18 does not have an increased spinout risk as long as it  
19 does not spin out under normal physiological loads.  
20 However, it is not clear to FDA how this modified  
21 physiological testing would correlate with the  
22 clinical mechanisms of this type of failure mode.

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1                   Separation of the patellar bearing from  
2 the metal base plate is an inherent risk associated  
3 with the design of the mobile bearing patellas. It is  
4 also a risk that is associated with fixed bearing  
5 patellas. As a result of the shear and torque forces  
6 experienced in the patella/femoral joint of the knee,  
7 there is a risk of patella bearing separation.

8                   To address this risk, the sponsor has  
9 proposed characterization of the component interlock  
10 strengths as recommended in the current fixed bearing  
11 knee guidance. These include static tensile pulloff  
12 testing, shear fatigue testing, and evaluation  
13 according to ASTM Standard F1672, which is the  
14 standard specification for resurfacing of patellar  
15 prostheses, although it is noted that this standard  
16 has no device-specific test methods to evaluate the  
17 performance of patellar prostheses.

18                   It is well known that successful  
19 implantation of mobile bearing knees is highly  
20 technique-sensitive. Without proper attention given  
21 to soft tissue balancing, instability of the implanted  
22 joint is a very real risk. To minimize this risk, the

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1 sponsor suggests that special attention should be  
2 given to providing appropriate instructions for use of  
3 the device in the product labeling.

4 The sponsor believes surgeon training and  
5 detailed surgical techniques that include instructions  
6 for proper soft tissue balancing will provide  
7 reasonable assurance of safety and effectiveness.

8 Although no specifics were given for these  
9 recommended controls, such as the requirements for  
10 training, it appears that these would include the same  
11 type of information currently provided for the fixed  
12 bearing knees.

13 The only risk identified as specifically  
14 unique to unicompartmental knees is that  
15 unicompartmental devices require an intact anterior  
16 crucial and posterior crucial ligament. To mitigate  
17 the risk of these devices being implanted in patients  
18 without functional crucial ligaments, the sponsor has  
19 recommended appropriate instructions for use in the  
20 product labeling and surgeon training in the proper  
21 surgical technique as ways to control this risk.

22 And, lastly, the risk of prosthesis or

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1 soft tissue impingement has been identified for mobile  
2 bearing knees. Impingement of the soft tissues can  
3 lead to soft tissue irritation, swelling, bleeding,  
4 and pain, and, again, this has to do with the mobile  
5 bearing nature of the tibula insert and patella  
6 bearings.

7 To control for this risk, the sponsor  
8 believes wear testing in a knee simulator and  
9 appropriate surgeon training with detailed surgical  
10 techniques that include proper instructions for use in  
11 the product labeling will provide a reasonable  
12 assurance of safety and effectiveness.

13 It is the potential occurrence of these  
14 adverse events or risks that we at FDA are responsible  
15 for evaluating. As such, we must have methods at hand  
16 to evaluate or mitigate these risks for all device  
17 types that are to be reclassified. Remember, to  
18 reclassify into Class II, we must have reasonable  
19 assurance of the safety and effectiveness of these  
20 devices.

21 And this is where we come back to the  
22 issue of special controls. The challenge for FDA will

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1 be to develop a special controls guidance document  
2 that can adequately address the risks identified for  
3 all mobile bearing knee types being reclassified. If  
4 special controls are not available or are insufficient  
5 to control these risks, then reclassification may not  
6 be an option.

7 FDA's primary concern is whether the  
8 proposed special controls are adequate to properly  
9 evaluate all of the mobile bearing knee designs  
10 covered by this reclassification petition, and whether  
11 they provide that reasonable assurance of safety and  
12 effectiveness.

13 Based on the information provided in the  
14 petition, FDA has some questions we'd like the panel  
15 to address in order to help us reach a decision on  
16 this reclassification petition. We ask for your  
17 recommendations on these questions after you have  
18 completed your discussion.

19 The questions focus on four general areas.  
20 I'll present the specific questions in just a moment,  
21 but the four areas of focus are the proposed  
22 classification definitions, the risks to health

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1 presented by mobile bearing knees, the ability of  
2 special controls to adequately control the risks  
3 associated with these devices, and the data presented  
4 and whether it supports the reclassification of the  
5 mobile bearing knees.

6 I will run through all of these questions  
7 for you now, and then come back to them one by one if  
8 needed later on as you address them following your  
9 discussion.

10 I will refer the panel members to their  
11 copy of the panel questions in the presentation packet  
12 you received this morning for the complete text of the  
13 questions. A few of these are somewhat lengthy and  
14 are paraphrased on some of these slides.

15 Question number 1: do you believe the  
16 proposed classification definitions for the following  
17 device configurations recommended for reclassification  
18 adequately describe the devices? If not, what changes  
19 in the definitions do you recommend? And, again,  
20 we're specifically talking about total mobile bearing  
21 designs and the unicompartmental designs.

22 A copy of the proposed classification

1 definitions are included with a copy of the panel  
2 questions, and I have also put them on the following  
3 two slides here. I'll read them to you now, and we  
4 can come back to them after the discussion, if we need  
5 to look at them.

6 The sponsor has proposed the following  
7 classification description for a total mobile bearing  
8 knee. A knee joint patellar/femoral, tibula, metal  
9 polymer, mobile bearing, cemented, or porous-coated  
10 uncemented prosthesis is a device intended to be  
11 implanted to replace the knee joint. The device  
12 permits either unconstrained or constrained rotation  
13 of the articular surface in the transverse plane, and  
14 may or may not permit limited anterior/posterior  
15 and/or medial/lateral movement of the articular  
16 surface upon the tibular component.

17 It has no linkage across the joint. The  
18 device may use a fixed structural porous metal in  
19 place of a porous coating. This generic type of  
20 device is designed for use with bone cement and/or to  
21 achieve biological fixation to bone without the use of  
22 bone cement.

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1                   And the following classification  
2 description has been proposed for the unicompartmental  
3 mobile bearing knee. It's a knee joint  
4 patellar/femoral, tibula, metal polymer, mobile  
5 bearing cemented or porous-coated uncemented  
6 prosthesis. It's a device intended to be implanted to  
7 replace part of a knee joint.

8                   The device permits either unconstrained or  
9 constrained rotation of the articular surface in the  
10 transverse plane, and may or may not permit limited  
11 anterior/posterior and/or medial/lateral movement of  
12 the articular surface upon the tibular component.

13                   It has no linkage across the joint, and  
14 the device may use a fixed structural porous metal in  
15 place of the porous coating. This generic type of  
16 device is designed for use with bone cement and/or to  
17 achieve biological fixation to bone without the use of  
18 bone cement.

19                   And on to question 2: do you believe the  
20 risks to health of the following device configurations  
21 proposed for reclassification are adequately  
22 described? If not, what additional risks do you

1 believe should be included?

2                   Question 3: special controls have been  
3 proposed to address the risks to health identified for  
4 both of the above-referenced device configurations and  
5 all related subconfigurations. Please respond to the  
6 following questions regarding specific risks and/or  
7 special controls.

8                   3A. Dislocation and subluxation of mobile  
9 bearing knee components have been cited as common  
10 complications in the literature. Do you believe  
11 appropriate special controls have been identified to  
12 adequately address these risks? If not, what  
13 additional controls, if any, do you recommend to  
14 address these risks?

15                   3B. A reduction in wear is often cited as  
16 a theoretical advantage of mobile bearing knees over  
17 fixed bearing knees. However, this has not been  
18 consistently demonstrated clinically, and it is not  
19 clear how well pre-clinical wear testing of mobile  
20 bearing knees correlates to the clinical situation.  
21 In fact, the potential for third body wear appears  
22 greater due to the fact that you have the two moving

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1 interfaces instead of one.

2           Currently, the state of development of  
3 knee simulator wear testing has not yet been  
4 standardized or clinically validated for all design  
5 types of mobile bearing knees, and, therefore, may not  
6 be applicable for all of the various mobile bearing  
7 knee types identified in this petition.

8           In light of the fact that wear appears to  
9 be in part design-dependent, do you believe  
10 appropriate controls have been identified to  
11 adequately address the risk of wear -- that is,  
12 osteolysis and loosening -- of the various mobile  
13 bearing knee designs under consideration in this  
14 petition? If not, what additional controls, if any,  
15 do you recommend to address this risk?

16           3C. Labeling has been cited as a method  
17 with which to control some of the identified risks to  
18 health. Proposed labeling requirements are consistent  
19 with those generally found in current fixed bearing  
20 knee package labeling.

21           Such labeling typically includes adequate  
22 instructions for use, device description, indications

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1 for use, contraindications, adverse events,  
2 precautions, warnings, listing of compatible  
3 components, and sterility information. What  
4 additional labeling, if any, do you recommend for  
5 these mobile bearing knee devices?

6 3D. Do you believe appropriate special  
7 controls have been identified to adequately address  
8 the risks to health for each of the above device  
9 configurations and the various subconfigurations? If  
10 not, what other special controls do you recommend to  
11 address the risks presented by these devices?

12 Question 4: do you believe the data  
13 presented in this petition supports the  
14 reclassification of all total mobile bearing knee  
15 prostheses identified in the petition? If not, which  
16 types of total mobile bearing knees do you believe are  
17 inappropriate for reclassification? And why?

18 And do you believe the data in the  
19 petition supports the reclassification of all  
20 unicompartmental mobile bearing knee prostheses  
21 identified in the petition? If not, which types of  
22 unicompartmental knees do you believe are

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1 inappropriate for reclassification? And why?

2 At this time, I would like to thank the  
3 panel for your time and attention. This concludes  
4 FDA's presentation. I will now turn the floor over to  
5 the Chair for discussion.

6 Thank you.

7 CHAIRPERSON YASZEMSKI: Thanks very much,  
8 Mr. Allen.

9 We're going to take a break in a minute,  
10 but I'd like to say before we break that when we  
11 return we'll start with the panel's review of this  
12 reclassification position led by Dr. Mayor and by Dr.  
13 Larntz. And we'll have the panel discussion and go to  
14 the questions.

15 It's now almost 10:05. Let's start again  
16 at 10:15, a 10-minute break.

17 (Whereupon, the proceedings in the  
18 foregoing matter went off the record at  
19 10:05 a.m. and went back on the record at  
20 10:18 a.m.)

21 CHAIRPERSON YASZEMSKI: Let's get back to  
22 the meeting. Dr. Michael Mayor is the former

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1 chairperson of this panel. He is going to open this  
2 part of the meeting with his remarks.

3 Then Dr. Kinley Larntz, our statistician,  
4 will give his remarks on the proposed reclassification  
5 from the statistician's perspective. The panel will  
6 then have a general discussion, after which they will  
7 focus their deliberations on the four FDA questions  
8 that you saw a minute ago. Then Ms. Shulman will  
9 guide us in the completion of two documents: the  
10 reclassification questionnaire and the supplemental  
11 data sheet forms. We will then conclude our  
12 deliberations.

13 I will also mention that after Dr. Mayor  
14 and Dr. Larntz speak, I am going to ask Dr. Witten to  
15 make some general comments about reclassification so  
16 that the panel can consider them as we go forth with  
17 our discussions.

18 I am going to ask Dr. Mayor to begin and  
19 give us his presentation. Dr. Mayor?

20 MEMBER MAYOR: Thank you, Dr. Yaszemski.

21 PANEL DELIBERATION AND RECOMMENDATION

22 MEMBER MAYOR: These observations that I

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1 will make are my own but are offered for consideration  
2 by the panel and FDA.

3 My sense is that the state of the art is  
4 comparable for both "fixed" -- and I have used "fixed"  
5 in quotes -- and mobile bearing total knees. Fixed  
6 and mobile bearing total knees as devices had with  
7 some exceptions proven to provide some of the most  
8 predictable and cost-effective interventions available  
9 to medical practice. Consensus standards have evolved  
10 to enhance the likelihood of evaluation of devices  
11 submitted for determination can be assessed  
12 appropriately.

13 Many of the considerations regarding where  
14 are common to both fixed and mobile bearings since  
15 unintended motion and wear have emerged as significant  
16 factors for the "fixed" bearing knees as well. It is  
17 not clear that mobile bearing designs emerged as a  
18 source of excessive risk regarding wear.

19 Stability represents another source of  
20 concern. In an effort to gain the advantages offered  
21 by mobile bearings, do we expose the general public to  
22 unnecessary, unacceptable risk? Past experience

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1 suggests that these risks are being addressed.

2 We, the panel, are being asked to  
3 determine if safety and effectiveness of mobile  
4 bearing knee devices can be adequately assured were  
5 they to be reclassified into the class II category.

6 With the means available to FDA including  
7 and not limited to available performance standards and  
8 test methods, extensive clinical experience documented  
9 in the literature, and established procedures for  
10 evaluation of devices brought to FDA for approval, it  
11 seems prudent and in adequate defense of the  
12 well-being of the general public to recommend to FDA  
13 the reclassification of mobile bearing knees that is  
14 the subject of this petition.

15 Additionally, the development of special  
16 controls and an appropriate guidelines document would  
17 be strongly supported.

18 Thank you.

19 CHAIRPERSON YASZEMSKI: Thanks very much,  
20 Dr. Mayor.

21 Dr. Larntz?

22 MEMBER LARNTZ: I'm going to make a few

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1 scattered comments as I might. Let me say, first off,  
2 I think statistical analysis is a wonderful subject.  
3 I think it is useful. And no matter what you do, you  
4 can be criticized, guaranteed.

5 Some of what I am going to say is in the  
6 form of some criticism, but if the positions were  
7 reversed, -- and sometimes they are -- the same kinds  
8 of criticisms might be leveled at work I would do. So  
9 I don't want to take this as too negative. Okay?

10 A basis for the reclassification we are  
11 going to do or some of the statistical evidence for  
12 that has to do with some meta analyses. Meta analysis  
13 is hard work. I have done enough of it to know that  
14 your work is never done. And wherever you stop, you  
15 could always do more. And you could always be  
16 criticized. So that is where we are with the meta  
17 analysis we have here, particularly meta analyses that  
18 are from literature that has got to be selective.

19 My gosh. How do these papers get  
20 published anyway? I was a university faculty member  
21 for 27 years. Boy, there was pressure on me to  
22 publish those papers, no matter what, no matter where.

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1 But it's selective. What gets published is selective.  
2 There's no question about that.

3 The literature, as was indicated in some  
4 of the presentations, is incredibly variable,  
5 incredibly variable. I would say, however, that that  
6 is the way life is. That is why statistics are so  
7 wonderful. Everything is incredibly variable.

8 By that token, we are looking at a  
9 comparison to say that mobile bearing and fixed  
10 bearing give similar results. Similar within the  
11 context of lots of variation is actually very easy to  
12 achieve. Do you hear what I am saying?

13 Similar in the context of lots of  
14 variation is very easy to achieve. So saying that  
15 they are similar doesn't mean that there is no  
16 difference between them. It means that we don't have  
17 evidence, enough evidence, of difference if there are  
18 differences.

19 There clearly is not enough or the  
20 literature is such that, as literature often is  
21 composed of many different studies, often quite  
22 scattered and published for different reasons. And,

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1 thus, it is very difficult to do a meta analysis that  
2 will give you any firm, firm results. So that, by the  
3 way, was preamble in some sense but conclusion also,  
4 by the way. So maybe I should stop. But I won't.

5 So, on the whole, I believe that the  
6 differences we see, the amount of difference we see,  
7 actually is an understatement of the variation that  
8 actually exists.

9 There are a couple of technical reasons.  
10 Those of you who aren't statisticians can turn off now  
11 for a second. I will tell you when to tune back in.

12 A couple of technical reasons. One is the  
13 analyses, the meta analyses, were done in what is  
14 called a fixed effects context. Each study has its  
15 own component.

16 If you look at tables -- and I'm not going  
17 to ask you to turn to page 277, but if you look at  
18 tables there are clearly variations. For instance,  
19 the percentage good, excellent varies from in the 30s  
20 to 100. Well, that's different. Thirty percent to  
21 100 percent. Do you believe that's different?

22 That's the kind of variation we have in

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1 these studies. So these studies are clearly  
2 statistically different. That is, they have random  
3 components that have to do with the studies  
4 themselves.

5 And they are probably inexplicable but  
6 need to be accounted for in any measure, any measure,  
7 of variation that is given. And in some sense, some  
8 of the statistical analyses do that, but doing a true  
9 random effects I think would answer that better,  
10 rather than a fixed effects meta analysis. That being  
11 said, I don't think that's too terribly important, but  
12 that is a technical comment.

13 There is also some amputation of data.  
14 Non-statisticians don't have to tune in yet. In  
15 addition, there is some amputation of data based on  
16 eight data points using regressions with five  
17 variables. Now, actually, non-statisticians tune back  
18 in because this might be something you might try to  
19 do.

20 If you have eight data points and you use  
21 five variables to predict them, guess what. You can  
22 do a very good job of prediction. And so when they

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1 report  $r^2$  values, which you have all heard  $r^2$ , that is  
2 a big number, right, like .8? With that kind of  
3 prediction, to me, that is the same as nothing. Okay?  
4 It's not statistically appropriate to make a big deal  
5 of that, and I will just leave that alone. Okay. So  
6 those are some small points. So understate the  
7 difference in variation.

8 I don't believe we have evidence that  
9 there are differences in anything with respect to  
10 these subjective scales of goodness. I worry a little  
11 bit about the survival meta analysis. Let me tell you  
12 a couple of things why.

13 In fact, we heard some interesting points  
14 about the survival. We said it is one percent per  
15 year. We heard that. In fact, we saw some very  
16 interesting documentation that that is about what it  
17 is. And, yet, the survival analysis itself, the  
18 actual meta analysis, as near as I can tell, takes no  
19 account of the individual follow-up time in the  
20 studies, as far as I can tell.

21 I looked and tried to figure that out. In  
22 fact, there are some answers to some questions the FDA

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1 raised about their analysis, and it looked like the  
2 actual study length time is not accounted for. And  
3 survival should be related to time, yes? But why  
4 wasn't it related to time in this? There's so much  
5 variation. You could find it's not statistically  
6 related to time because of the amount of variation in  
7 these studies.

8 Did you see the side by side comparison  
9 that was up there? And you saw a whole bunch of  
10 things. Maybe you said, "I will tune out." It was  
11 kind of hard to see, but if you looked, a lot of the  
12 data points were to the right, toward 100, right,  
13 toward 100 percent survival. But there were a few.  
14 In fact, a couple were highlighted in red, right? Do  
15 you remember that? There were a few that were on the  
16 other side.

17 These are very different values, and they  
18 are all being combined. They are all being combined.  
19 This is the kind of variation that is being combined.

20 So that is just a couple of minor points.  
21 I don't know that there is no difference in survival.  
22 Look, I am here criticizing. My gut feeling is they

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1 are probably pretty much the same. Okay? But that is  
2 my gut feeling. I am a statistician. I am not  
3 allowed to have gut feelings. So ignore that comment.

4 Let me make a couple of other comments.  
5 And then I will be quiet. There were some bootstrap  
6 technical comments. If bootstrapping is done, I would  
7 rather do a randomization test. That is a minor  
8 detail. Okay. Leave that alone.

9 One meta analysis that was not done that  
10 I worried about is a meta analysis on adverse event  
11 rates. It looked like to me -- now, maybe you have  
12 done something, but I didn't see a meta analysis of  
13 adverse event rates.

14 I think adverse event rates would be very  
15 important, but there was also some information in my  
16 adverse events with respect to some of the studies, at  
17 least that I could tell. And there was one group of  
18 studies that had much higher adverse event rates, if  
19 the medical people would help me understand why that  
20 is true. There were studies called PCL sacrificing;  
21 that is, devices that do whatever that is. Okay?

22 They look to be much worse. That's at

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1 least from the data that was provided, much worse.  
2 And, yet, when the meta analyses were put together, as  
3 near as I can tell, they were lumped in with  
4 everything else, as near as I could tell. And, yet,  
5 there is a variable or a kind of device or a kind of  
6 study or whatever it is. And I am just a  
7 statistician. So I don't know what. They called it  
8 PCL sacrificing. Okay? That, in fact, looked to be  
9 a variable that was a very big effect on adverse event  
10 rates, on survival, and so on. But as far as I could  
11 tell, that wasn't taken account of in the meta  
12 analysis.

13 Now, all of that said, I think it is also  
14 interesting that we actually only have three approved  
15 PMAs for this device already. That is not a very big  
16 experience set. I will just say that. What I am  
17 going to do is -- oh, you are all waiting for me to  
18 stop.

19 There is one last group of reporting that  
20 actually is very minor, but when I do meta analysis,  
21 I try to identify the specific studies that are in the  
22 meta analyses, right, specific articles. I will give

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1 a good name, like it's done by Larntz, et al. That  
2 would be a good study, I am sure, a perfectly good  
3 study. Okay?

4 But in the reporting, the number of the  
5 reports were study 1, study 2, study 3, study 22. For  
6 instance, without great effort, -- and I didn't make  
7 that great effort -- I can't tell which of those 22  
8 studies were PCL sacrificing. For instance, in that  
9 reporting, I think when we do a meta analysis, it  
10 behooves you to make sure you keep emphasizing the  
11 source of your information.

12 And the way you do that is by keeping  
13 reminding people which of these studies are all the  
14 labels. When you do the 37 in the survivorship, 22 in  
15 the first one, all of these should be labeled. Minor  
16 point in the end.

17 I am not sure I said anything except there  
18 is a lot of variation. I think it is very difficult  
19 to make any conclusions from the meta analysis.  
20 Saying that everything is the same or statistically  
21 saying that there is no difference is not the same as  
22 saying there is no difference.

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1 I will be quiet. Thank you.

2 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
3 Larntz. I will thank both Dr. Mayor and Dr. Larntz  
4 for giving their reviews.

5 What we are going to do now is I am going  
6 to ask Dr. Witten to give some general comments from  
7 the FDA's perspective on classification so that we all  
8 understand what we are being asked to do.

9 Then we are going to have a session -- and  
10 I will suggest it be a short session -- on any general  
11 comments before going specifically to the questions.  
12 During either the general comment session or the  
13 specific question session, any panel member may  
14 request that FDA representatives or sponsor  
15 representatives give an answer to specific questions  
16 that they may have.

17 Let's start now. Dr. Witten, could I ask  
18 that you make some comments about reclassification?

19 DR. WITTEN: Yes. I just want to clarify.  
20 Thank you.

21 I just want to clarify what our goal is  
22 here today. Hopefully these were clarify it more and

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1 not confuse it more. Let me just say that when you  
2 consider reclassifying a device type, you reclassify  
3 based on the devices that FDA has approved.

4 So the ones we would be reclassifying are  
5 based on what we have approved. But all of the other  
6 designs that have been presented would be devices that  
7 then potentially would be eligible for coming in under  
8 this regulatory route of class II devices.

9 So our discussion or what we are hoping  
10 for from you is not really so much a discussion about  
11 whether or not these devices are safe and effective  
12 but whether or not we understand enough about the test  
13 methodology and its ability to predict device  
14 performance to be able to adequately control the risks  
15 and regulate these devices. So it's more the risks  
16 and the test methods, rather than, are the devices  
17 safe and effective.

18 Maybe that was already clear.

19 CHAIRPERSON YASZEMSKI: Thank you. Thank  
20 you for the clarification.

21 Let's go around the table one time with a  
22 general discussion. In a moment, I am going to ask,

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1 Dr. Kirkpatrick, that we start with you. I am going  
2 to pose a topic for the discussion. It seems that  
3 through these presentations by the FDA and by the  
4 sponsor, there does exist a question as to whether all  
5 mobile bearing knee devices can be considered alike;  
6 that is, those that have unidirectional motion versus  
7 those that have multidirectional motion.

8 I want to go around the table and ask  
9 everybody what they think about that. Should we  
10 address all of these as a single class or might they  
11 be separated? Let's get that out before we start  
12 answering the questions.

13 Dr. Kirkpatrick?

14 MEMBER KIRKPATRICK: So you want to answer  
15 that question before I ask a question of the sponsor  
16 that may be related?

17 CHAIRPERSON YASZEMSKI: You decide how you  
18 want to go, but I would like to hear your comments on  
19 that sometime before we go to Dr. Mabrey.

20 MEMBER KIRKPATRICK: So your question  
21 specifically was, are mobile bearing unicondylars the  
22 same as mobile bearing total --

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1 CHAIRPERSON YASZEMSKI: No. Are any  
2 mobile bearing devices in which there is only motion  
3 type; i.e., rotation only, appropriate to be  
4 considered together with all other types that may  
5 rotate and translate and have multidirectional motion,  
6 as we have heard from many of the presenters this  
7 morning that sometimes the multidirectional mobile  
8 bearing devices more are like a hip device in their  
9 wear characteristics than a single bearing type mobile  
10 bearing device?

11 I would just like to have everybody  
12 comment on that, in addition to their questions. So  
13 go ahead with your questions, but do comment on that.

14 MEMBER KIRKPATRICK: My comment on that  
15 would be I think you have got to test in more than one  
16 direction if the device allows more than one  
17 direction. I think that a device that allows more  
18 than one direction is somewhat different than one that  
19 just allows one direction.

20 CHAIRPERSON YASZEMSKI: Thank you. That  
21 is what I wanted.

22 MEMBER KIRKPATRICK: Now, I do have a

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1 question for the sponsor if it's okay. And I think it  
2 relates somewhat to this. I have to apologize. I am  
3 not quite as smart as the sponsor's people or perhaps  
4 even the panel, but I am having a difficulty  
5 understanding one concept with what you presented. To  
6 put it into some understanding, I have to relate to  
7 something I can understand.

8 I cover a football team in the fall. We  
9 were the state champions this past year, but we lost  
10 our opening game against a cross-town rival because on  
11 two defensive plays, a single missed assignment by one  
12 player on one play and another player on another play  
13 resulted in two scores and we lost by those two  
14 scores.

15 Now, you have presented an extensive  
16 amount of data. However, you have eliminated two  
17 devices that are both mobile bearing knees. As I  
18 understand, the Oxford one and the Accord were  
19 excluded from your device analysis. And then you take  
20 after the elimination of that all of the remaining  
21 data and say everything else is similar.

22 My concern is that if we go with this

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1 reclassification, then we won't be including some of  
2 the devices that should be included. Can you help me  
3 understand the rationale for excluding those two  
4 devices, so that I can better put this into context?

5 DR. STIEHL: I think that is a very, very

6 --

7 CHAIRPERSON YASZEMSKI: Dr. Stiehl, excuse  
8 me. For the transcription, would you just state your  
9 name?

10 DR. STIEHL: Sure. Dr. Jim Stiehl.

11 As I understand the issue here, we are  
12 trying to figure out, can we pick those two problems  
13 out of this group and say, "All right. These are  
14 going to be problem implants. You are going to have  
15 to look at these implants very carefully"?

16 There were issues with the Accord device  
17 a number of years ago that made it unsuitable as a  
18 mobile bearing device. I mean, it is old. I don't  
19 even know what it looks like. I have been told it  
20 relates to the stability device and that sort of  
21 thing.

22 I think the challenge here for us is to

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1       decide if we can pick out that particular device as a  
2       problem device.    The Oxford I, for example, is a  
3       unicondylar device.  They kind of sprayed it at first.  
4       But then they figured out the device worked very, very  
5       well if they had fairly stringent criteria of a  
6       retained ACL, certain amounts of deformity not used on  
7       the lateral side and that sort of thing.  So they  
8       refined their experience with it so then they could  
9       pick up what that problem was.  Then it is okay.  Now  
10      you see a free market approval of that particular  
11      device.

12                    I think the challenge here is, can we look  
13      at devices and know they are going to be okay or not?  
14      That is really what this special controls issue is.

15                    We have an extraordinary amount of  
16      knowledge about mobile bearing knees because they have  
17      been out there for 30 years.  In the last five to ten  
18      years, my colleagues have shown an extraordinary  
19      amount of information about how total knees in general  
20      work.  I mean, my area and Doug Dennis' has been in  
21      the area of kinematic research.  We have learned  
22      things looking at these mobile bearings that we didn't

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1 know before, but they certainly will guide us in what  
2 we will be thinking about in the future.

3 For example, all mobile bearings aren't  
4 alike. I mean, there are certain features that cause  
5 some concern, like this multidirectional issue. Now,  
6 it may be fine with the Corin knee, the Rotaglide.  
7 The Rotaglide has an extraordinary and a long-term  
8 experience. I mean, it is a good device. The AP  
9 Glide, on the other hand, where it can just slide  
10 forward as far as it wants to go without any checks,  
11 may be a problem.

12 Soft tissue impingement really wasn't  
13 recognized with any knee device of considerable  
14 concern. Now with mobile bearings, I think soft  
15 tissue impingement is a concern. So that special  
16 control is a very important issue.

17 And when we discussed our presentation  
18 here before this panel, I was very adamant that that  
19 particular concern has to be addressed as a special  
20 control. So we have to know that that is okay.

21 I believe that we are close to knowing  
22 pretty much how these knees work well. We are

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1 refining how we get surgeons to use these knees. But  
2 there is some ease with which we do this.

3 I think in your experience, it would be  
4 much easier to take a fixed bearing knee that you  
5 understand very, very well and the technique and all  
6 of that and then say, "Well, I am going to add a  
7 mobile bearing to this device." I mean, that is a  
8 small increment of a step. And you can understand how  
9 that might work.

10 That, in effect, is what has happened with  
11 the PFC signal, which has a supplemental pre-market  
12 approval. The surgeons that use the PFC signal can  
13 essentially do that. They can know their fixed  
14 bearing technique very well. Then they can add this  
15 mobile bearing to that construct and make it work with  
16 some ease.

17 Other devices, it is not going to be as  
18 easy to do, particularly the LCFs because they had a  
19 unique technique. It was a unique design. And you  
20 had no fallback if the mobile bearing didn't work.

21 So these are issues that we understand.  
22 And I honestly believe that I as a surgeon can pick up

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1 a good mobile bearing when I see it and a bad mobile  
2 bearing that I wouldn't like if I saw it. And I think  
3 the engineers have a lot of experience with testing to  
4 show you some of these efficacy issues.

5 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
6 Stiehl.

7 MEMBER KIRKPATRICK: May I just follow up  
8 with a quick question --

9 CHAIRPERSON YASZEMSKI: Yes.

10 MEMBER KIRKPATRICK: -- of both the  
11 sponsor and the FDA? Can you provide me the specific  
12 current standards that would have kicked out both the  
13 Oxford one and the Accord?

14 CHAIRPERSON YASZEMSKI: Mr. Allen, do you  
15 want to lead that off? And I will ask somebody from  
16 OSMA to be prepared.

17 MR. ALLEN: Pete Allen, FDA.

18 As far as the Accord, as Dr. Stiehl said,  
19 I am not real familiar with the design. And I don't  
20 know specifically what the issues were with that one.  
21 As far as the early Oxford devices, as Dr. Stiehl  
22 said, I think it was a learning curve of a design that

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1 they discovered what some of the problems were as far  
2 as the way they were indicating it for use.

3 I can't think of any specific preclinical  
4 tests that could have caught that ahead of time.

5 MEMBER KIRKPATRICK: So if I could  
6 summarize my understanding, we do not have current  
7 specific standards which would have identified the two  
8 devices that OSMA has eliminated from their  
9 presentation?

10 MR. ALLEN: Not to my knowledge.

11 MEMBER KIRKPATRICK: Thank you.

12 CHAIRPERSON YASZEMSKI: Thanks.

13 Dr. Walker, would you like to comment on  
14 that? Thanks, Mr. Allen.

15 DR. WALKER: That is an excellent  
16 question, which gets to the heart of testing methods.  
17 In other words, the test method must eliminate the  
18 potentially defective devices. In fact, a history of  
19 defective devices is a very good way to validate a  
20 test.

21 In other words, a test that we would come  
22 up with to look at bearing dislocation, for example,

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1 or instability would have to fail the Accord and  
2 appropriately fail the early version of the Oxford.

3 For example, without writing the test or  
4 without writing the standard, if you like, or writing  
5 the guideline at this time, one could say just quickly  
6 that any device which is unconstrained in all  
7 directions, for example, using the existing constraint  
8 test, any device which is unconstrained in all  
9 directions should simply not be allowed. I mean, that  
10 would be a no. I mean, it's that simple because we  
11 have evidence of that, a device which is unconstrained  
12 and so on.

13 So I think that the test has to be  
14 devised, as I said, using the body of knowledge we  
15 already have. And I think that the Oxford is a  
16 special case. It has been approved already, the PMA.

17 The Oxford is a special case in the  
18 following way, that, really, if it does not have any  
19 other stability associated with it, it would  
20 automatically just dislocate front to back. But the  
21 surgeons who have used it and, in fact, the  
22 specifications have been very, very clear on

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1 specifying the surgical technique, that it has to have  
2 ACL/PCL and that the surgical technique has to be very  
3 rigorous, it has to be restricted to the medial side,  
4 which is tighter. The lateral side is not allowed if  
5 you notice.

6 So, again, I think using the experience  
7 like that, I think one can, one could quite easily  
8 eliminate designs that are simply too unstable.

9 MEMBER KIRKPATRICK: Your first comment I  
10 can't agree with because we just voted approvable a  
11 device that has no constraint in any direction  
12 yesterday.

13 DR. WALKER: Well, I can take your point.  
14 I did make a caveat of saying, though, that, you see,  
15 the Oxford in a way is unique in the sense that it is  
16 not just a device. It is combined with the ACL and  
17 the PCL and the medial side. I think in a way, that  
18 is a special case that would have to be made  
19 specially.

20 So, you know, I don't think any test can  
21 cover every conceivable variation. I mean, I think we  
22 are kidding ourselves if we say that.

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1 MEMBER KIRKPATRICK: My concern as a panel  
2 member is, can we establish and define a special  
3 control today that would cover those two devices?

4 DR. WALKER: I would say yes. If we sat  
5 down and we carefully documented it, I believe we  
6 could.

7 MEMBER KIRKPATRICK: But it does not exist  
8 at this point?

9 DR. WALKER: It exists in the minds of  
10 individuals who would have put it together.

11 MEMBER KIRKPATRICK: I think we will just  
12 go back and forth if I continue.

13 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
14 Kirkpatrick.

15 Dr. Mabrey?

16 MR. MAISLIN: I just wanted a  
17 clarification.

18 CHAIRPERSON YASZEMSKI: Mr. Maislin, come  
19 up. Yes?

20 MR. MAISLIN: I just wanted to clarify  
21 that. And it doesn't go to your main point, which is  
22 very well-taken, that, in fact, the summaries that

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1 were presented did not exclude those two.

2 The analysis, the summary analysis, that  
3 was on the first slide and the last slide included all  
4 of the mobile bearings. Analysis was repeated  
5 excluding those, but those weren't highlighted. The  
6 summary statistics that were presented did include the  
7 two devices that are now obsolete.

8 CHAIRPERSON YASZEMSKI: Thanks, Mr.  
9 Maislin.

10 MEMBER KIRKPATRICK: That's my mistake if  
11 I --

12 MR. MAISLIN: Right.

13 MEMBER KIRKPATRICK: If it was only for  
14 certain parts of your analysis since you excluded  
15 those, I apologize.

16 MR. MAISLIN: Yes, yes. The 90-some  
17 percent success rate included them. There was one  
18 slide that excluded them as a secondary analysis. And  
19 the success rate increased to about 93 percent. But  
20 to be conservative, I included in my main presentation  
21 all of the data that was available.

22 CHAIRPERSON YASZEMSKI: Thanks, Mr.

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1 Maislin. Sir?

2 DR. EMERSON: Yes. My name is Roger  
3 Emerson. I am an orthopedic surgeon. I have come  
4 here with Biomed. I am familiar with the Oxford knee  
5 and participated in the original IDE from this  
6 country.

7 Just a point of clarification. The design  
8 of the Oxford has not changed that much over the three  
9 phases, but the instrumentation, the understanding of  
10 how to implement mobile bearing has become more  
11 sophisticated. So it was appreciated very quickly  
12 that the phase I while the design could work was  
13 unpredictable. And precision had to be added.

14 Basically, the phase II involved a change  
15 in instrumentation that allowed incremental balancing  
16 of the soft tissues and then an appreciation of the  
17 role of the ACL in the stability of the  
18 unicompartmental knee.

19 CHAIRPERSON YASZEMSKI: Thank you.

20 MEMBER LARNTZ: May I follow up?

21 CHAIRPERSON YASZEMSKI: Sure. Go ahead,  
22 Dr. Larntz.

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1                   MEMBER LARNTZ: I was just going to follow  
2 up on your question. At what point did you realize it  
3 was unstable? I am just asking the last, following up  
4 on the last, comment. You said it was clear it was  
5 unstable. At what point did you realize that? When  
6 it was in the lab? When it was in the knee? After  
7 surgeries?

8                   DR. EMERSON: Well, this was in the 1970s.

9                   MEMBER LARNTZ: Right, sure.

10                  DR. EMERSON: So it was a different era.  
11 And there were being implanted both as a  
12 bicompartamental and as a unicompartmental implant. In  
13 the bicompartamental situation, you are juggling both  
14 sides of the knee.

15                  Basically, the survivorship of the  
16 bicompartamental was in the range of 80 percent.  
17 Survivorship of the unicompartmental back then was in  
18 the range of the high 80s and 90 percent.

19                  MEMBER LARNTZ: Excuse me. At what time  
20 period --

21                  DR. EMERSON: This was at a time when we  
22 didn't understand soft tissue balancing.

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1 MEMBER LARNTZ: You said 80 percent. Is  
2 that 80 percent after a month, 80 percent after 5  
3 years?

4 DR. EMERSON: The implant came out in  
5 1976. And the phase II came out in the mid '80s. So  
6 it was over a ten-year period.

7 MEMBER LARNTZ: So over a ten-year period,  
8 you realized it was unstable?

9 DR. EMERSON: Yes. The survivorship --

10 MEMBER LARNTZ: That's what I need to  
11 know.

12 DR. EMERSON: Yes.

13 CHAIRPERSON YASZEMSKI: Okay. Thanks very  
14 much.

15 Let's move on, Dr. Mabrey.

16 MEMBER MABREY: Just for clarification,  
17 you are asking me, do I think there is a difference  
18 between mobile bearing knees and fixed?

19 CHAIRPERSON YASZEMSKI: No, that is not  
20 what I am asking. When we get to --

21 MEMBER MABREY: Okay. The two --

22 CHAIRPERSON YASZEMSKI: When we get to

1 voting, is it appropriate in your opinion to vote for  
2 all mobile bearing designs as a general design that  
3 the FDA would then consider whether to allow as class  
4 II's or might there be distinctions between mobile  
5 bearing designs that we might recommend to the FDA  
6 that we separate? That's what I would like to hear  
7 from you.

8 MEMBER MABREY: Okay. I think in answer  
9 to that, you have to take into account that these are  
10 not just devices. These are systems. And, as some of  
11 the previous speakers have pointed out, the actual  
12 design of the implant may be ideal. And it could have  
13 performed quite well in the lab. Yet, once it was  
14 implemented with the early instrumentation, it proved  
15 not to be so feasible.

16 So to say that one design is equal to  
17 another or essentially equivalent, you have to take  
18 into account the history of those devices, the history  
19 of the designers, and I would say that there are  
20 subtle differences as far as the types of wear that  
21 might be generated. But I have to say that from my  
22 personal experience, I haven't seen a clinical

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1 difference between them.

2 CHAIRPERSON YASZEMSKI: Specifically, do  
3 you think that we could recommend to FDA special  
4 controls all of the possible types of mobile bearing  
5 designs?

6 MEMBER MABREY: I think that might be  
7 difficult based upon what we know today because we  
8 need to anticipate all possible future  
9 implementations.

10 CHAIRPERSON YASZEMSKI: Okay.

11 MEMBER MABREY: I am not supposed to say  
12 that, am I? Okay. It cut me off. I think that  
13 getting back to Earth here, to anticipate current  
14 designs, problems with current designs, I believe that  
15 there are adequate tests available now that could pick  
16 up gross problems with that design. I don't think  
17 that we can ever predict how it will perform  
18 clinically until it's actually been in use for some  
19 time.

20 CHAIRPERSON YASZEMSKI: Thank you. Other  
21 comments, Dr. Mabrey?

22 MEMBER MABREY: No.

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1 CHAIRPERSON YASZEMSKI: Dr. Finnegan?

2 MEMBER FINNEGAN: In answer to your  
3 question, yes, I do think we probably do need to split  
4 some things out.

5 I have three questions. The first  
6 question is for Mr. Maislin. On your scales, you  
7 spoke about how you picked the global rating scale  
8 that you used. You sort of nicely skipped over the  
9 fact that there is a statistically significant  
10 difference between the two groups that you compared in  
11 the percent global rating scale improvement. It was  
12 100 percent in the fixed. It was, I believe, 91.4  
13 percent in the mobile. Can you explain that?

14 MR. MAISLIN: Yes. That difference is  
15 actually quite small. It is not 100 percent of  
16 patients and 91 percent of patients. It's the percent  
17 improvement. It's as if there is a score that goes  
18 from 45 to 90. And that would be a 100 percent  
19 increase or 45 to 87. And that would be a 91 percent  
20 increase. And in those two cases, the clinical  
21 significance of an increase from 45 to 87 is probably  
22 trivial compared to one that went from 45 to 90.

1                   MEMBER FINNEGAN: Did you have range or  
2 median? Because I noticed you start it. So I'm  
3 assuming that meant there was some statistical  
4 significance.

5                   MR. MAISLIN: No, no. The table was  
6 repeated from the reclassification petition as is.  
7 The star indicated that that was raw data, that there  
8 wasn't -- I remember the subject test indicated that  
9 it was raw data. It wasn't an indication of any  
10 statistical significance.

11                   MEMBER FINNEGAN: Did you have a range or  
12 a median for either group?

13                   MR. MAISLIN: I don't know what those  
14 values are offhand. The actual data is in the  
15 reclassification petition, but I don't know. I assume  
16 that it's as variable as Dr. Larntz might suggest, and  
17 it was probably comparable in variability to the  
18 percent improvements.

19                   MEMBER FINNEGAN: Okay. Thank you.

20                   The next question is for Dr. Stiehl. You  
21 talked about in one of your slides the unis had a 6.8  
22 percent revision rate at four years. Can you --

1 DR. STIEHL: That was the phase II uni  
2 experience that I guess has already had a PMA  
3 approval. That's the device that we're talking about.

4 MEMBER FINNEGAN: Right. And was that  
5 related to age? Was it related to mechanical axis?  
6 Do you have any idea what the cause of that was?

7 DR. STIEHL: I can only refer to Roger  
8 behind me because he probably knows, but I think the  
9 failure rate with that particular series relates to  
10 its unis. And they failed earlier because they get  
11 lateral compartment disease and that sort of thing.  
12 I honestly don't know what their results were related  
13 to.

14 MEMBER FINNEGAN: So, Dr. Emerson, was  
15 this a pre-PMA IDE or was this part of the PMA IDE?

16 DR. EMERSON: That was all in the PMA for  
17 the original, for the phase II Oxford that has been  
18 approved. But the two figures were given. One was  
19 the figure for all revisions for any reason. That  
20 included lateral compartment disease, patella/femoral  
21 problems, inflammatory issues. And then there was a  
22 statement about the percentage failure for a revision

1 rate simply for bearing-related issues, which was the  
2 smaller number.

3 MEMBER FINNEGAN: Correct. But for all of  
4 your knees, it was 6.8.

5 DR. EMERSON: That 6.8 was actually  
6 reported at 2 years. There were 8 out of 117. It was  
7 two-year data. Also in the petition, there is data  
8 from two to eight years. And the figure there is a  
9 4.8 percent revision rate for bearing-related problems  
10 or implant-related problems of any kind, excluding  
11 lateral compartment, patella/femoral, inflammatory  
12 issues.

13 MEMBER FINNEGAN: What is the whole for  
14 all?

15 DR. EMERSON: 4.8 percent for the IDE out  
16 to 8 years for bearing-related.

17 MEMBER FINNEGAN: Right.

18 DR. EMERSON: 15.7 percent.

19 MEMBER FINNEGAN: For total?

20 DR. EMERSON: For a total.

21 MEMBER FINNEGAN: Thank you.

22 And then my general question to the

1 sponsor is Dr. Larntz brings up a wonderful point.  
2 Can you pull out the PCL sacrificing problems? And  
3 are you aware of them? And do you have any comments  
4 on that?

5 CHAIRPERSON YASZEMSKI: Dr. Stiehl?

6 DR. STIEHL: Yes, Jim Stiehl back.

7 Dr. Larntz, I think you are referring to  
8 the Callaghan meta analysis that looked at PCL  
9 sacrificing as being a problem area, as I recall.

10 MEMBER LARNTZ: I thought it was among  
11 your 22 studies. There were five of them that were  
12 PCL sacrificing, if I remember right. I mean, I was  
13 looking at your table. I think of the 22 studies, I  
14 think there are mobile bearing studies. There are 22  
15 studies. I will find the page in just a second. I  
16 will tell you.

17 DR. STIEHL: Well, the issue really is the  
18 rotating platform, which from my knowledge, at least  
19 of the LCS has been the standard of this standard  
20 concept, is a PCL sacrificing system.

21 Now, as I say, I'm aware in the Callaghan  
22 study, they definitely flagged PCL sacrifice as a

1 lower number.

2 MEMBER LARNTZ: This is in your meta  
3 analysis of your 22 studies. It says 14 are PCL  
4 sparing, 5 are PCL sacrificing. I am on page 282 in  
5 the document I have anyway if people want to find it,  
6 282 in volume I. And three are mixed prostheses.

7 For instance, numbers that are there,  
8 revision rates are 5.6 for the sparing and 9.2 for the  
9 sacrificing. Mechanical failure is 1.5 for the  
10 sparing and 5.2 for the sacrificing. There are  
11 revisions for bearing location break and subtraction,  
12 zero for the sparing, 2.8 for the sacrificing.

13 This is your table in your analyses. And,  
14 as far as I know, nothing was sorted out with respect  
15 to that covariate in the meta analyses except your  
16 report. Like I say, your report gave me information.  
17 I couldn't have found this myself because I couldn't  
18 have delved through all of that. So it seems to me  
19 there is something going on, at least with respect to  
20 those studies.

21 DR. STIEHL: I am going to have to --

22 CHAIRPERSON YASZEMSKI: Does that satisfy

1 your question, Dr. Finnegan?

2 MEMBER FINNEGAN: Yes.

3 CHAIRPERSON YASZEMSKI: All right.  
4 Thanks, Dr. Stiehl.

5 Let's come back. Let's wait until we come  
6 to Dr. Larntz. Then we'll have that discussion again.  
7 Let's go to Dr. Kim.

8 MEMBER KIM: I'm going to try to address  
9 the question that you asked, which is so that I  
10 understand it. These devices, can they be all grouped  
11 together into a single --

12 CHAIRPERSON YASZEMSKI: Right. Can we  
13 adequately suggest special controls that will cover  
14 all mobile bearing devices?

15 MEMBER KIM: That depends on the answer to  
16 whether or not we can get special controls because in  
17 my mind, I don't understand enough about the various  
18 intricacies of the mobile systems to be able to  
19 separate out one mobile system to another.

20 So my feeling is that I think it is okay  
21 to jump them all together. What we need to work on is  
22 whether or not we can devise special controls to look

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1 at all of the special design, all of the different  
2 designs.

3 CHAIRPERSON YASZEMSKI: Okay. Thank you.  
4 Dr. Naidu?

5 MEMBER NAIDU: I'm not sure we can lump  
6 them all together. I think inherently these devices  
7 are different systems, just like Dr. Mabrey has  
8 referred to. I think these devices have to be  
9 addressed as a system. I think they are all  
10 inherently different.

11 And from the presentations of the sponsor,  
12 some of the multidirectional platforms' survival rates  
13 are as low as 75 percent at 5 years. And all of the  
14 literature that Dr. Stiehl refers to, it seems like it  
15 points to the LCS.

16 So I think there is an inherent difference  
17 between the two. I am not sure that we could come up  
18 with the special controls document.

19 CHAIRPERSON YASZEMSKI: Okay. Thanks, Dr.  
20 Naidu.

21 Dr. Mayor?

22 MEMBER MAYOR: I'm going to suggest

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1 something that might sound a little semantically  
2 picky, but it comes from my experience with the ASTM  
3 documents with relate to constraint.

4           The documents that we have been reviewing  
5 identify a class of devices which have no linkage  
6 across the joint. I would suggest we either change  
7 that to these devices have no across the joint  
8 linkage.

9           I recognize that some of you may think  
10 that there is no difference in those two wordings, but  
11 my feeling is that, first of all, it would be more  
12 compatible with the ASTM documents as I remember them  
13 contained. And the term across the joint linkage is  
14 more specific to a mechanical design which binds the  
15 two parts together; whereas, linkage across the joint  
16 could be interpreted more loosely and could be taken  
17 to imply other kinds of mechanical interactions  
18 between the two parts. It's a small but I think  
19 useful point.

20           The other thing about the definitions is  
21 that in relationship to the tricompartamentals, there  
22 isn't a specific mention of whether or not the

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1 patellar interface is going to be mobile bearing or  
2 not.

3 I think the option needs to be included in  
4 terms of the device design that the patella could  
5 include a mobile bearing or might not. So the  
6 patellar devices that the designer might elect are  
7 identified as applicable in the reclassification if,  
8 in fact, that comes to be true.

9 My sense is that issues of dislocation and  
10 subluxation can probably be adequately addressed with  
11 careful attention to the patient in certain variables,  
12 the soft tissue issues that have been cited and  
13 discussed fairly extensively in the presentations from  
14 both sides of the issue.

15 I think in terms of wear phenomena, the  
16 thing I see as serious and missing in the discourse is  
17 the variations in polyethylene, that we know from our  
18 experience with all of the implants that have been  
19 studied, that polyethylene behaves differently  
20 depending on the resin from which it is derived, the  
21 processing used to bring it to its final form, and the  
22 steps that are taken subsequent to that to sterilize

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1 it and store it.

2 Without some acknowledgement of the impact  
3 on survivability of these implant components  
4 addressing the issue of polyethylene variability, I  
5 think we have missed an opportunity to protect the  
6 public from the kinds of things that we now begin to  
7 understand better and better as they relate to  
8 polyethylene and its variability.

9 The labeling I think needs to be looked at  
10 carefully because of the issues we have already  
11 discussed in terms of predictability of outcome. And  
12 that includes issues related to both the patient and  
13 the surgeon involved in the interaction.

14 As regards configuration and the  
15 subconfigurations, can they be adequately controlled  
16 by special controls and the guidance documents? I  
17 think they can. I think we need to discuss in some  
18 detail how that might be done and how to address that  
19 extra step that needs to be taken to make sure that we  
20 are responsible in our deliberations.

21 In response to Dr. Yaszemski's specific  
22 question, do I think that wear issues need to be

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1 addressed differently for "unidirectional" and  
2 multidirectional mobility in bearing design, no. I  
3 think we can address with a fairly monolithic document  
4 the issues that relate to both of those.

5 CHAIRPERSON YASZEMSKI: Thanks very much,  
6 Dr. Mayor.

7 Dr. Larntz?

8 MEMBER LARNTZ: On your primary question,  
9 I don't have any evidence to give an opinion. Do you  
10 want me to follow up with these people and give them  
11 --

12 CHAIRPERSON YASZEMSKI: At your  
13 discretion.

14 MEMBER LARNTZ: To talk to me about page  
15 282? We can do that for -- do you have a timer on? --  
16 no more than three minutes.

17 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
18 Larntz.

19 MEMBER LARNTZ: I will let you respond to  
20 what is on page 282.

21 CHAIRPERSON YASZEMSKI: Mr. Maislin?

22 MR. MAISLIN: Thank you.

1 I want to point out one item that the  
2 stratification by PCL status was not something that  
3 was uncovered. It was an attempt by the investigator  
4 who implemented this meta analysis to follow  
5 Callaghan.

6 And since Callaghan did it, they did it,  
7 just to let you know why it was stratified. In fact,  
8 the later analysis didn't emphasize it because it  
9 wasn't something that was interesting. It appears  
10 primarily because they were following a recipe of an  
11 analysis that was published.

12 MEMBER LARNTZ: And I think I understood  
13 that. I'm not sure that is always the best thing to  
14 do.

15 MR. MAISLIN: I agree.

16 MEMBER LARNTZ: But let me just point out  
17 -- and I think this is what Dr. Finnegan might want to  
18 look at on page 282. I mean, complication rate in  
19 knees, any complication rate, 5 percent with sparing  
20 and 14.1 percent, now, I don't know if those are  
21 significant because there is tons of variation here.  
22 There is tons of variation.

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1           But I am saying it seems to me -- and I  
2           didn't have the comparable numbers from the Callaghan  
3           fixed to compare that to, I don't think. I don't  
4           think I have that here.

5           MR. MAISLIN: I don't know.

6           MEMBER LARNTZ: I think this is your  
7           study. These are your man-hours. So there are not  
8           comparable numbers. I know if Callaghan found that in  
9           the fix, then I think it would be important to think  
10          about that kind of stratification here and kind of  
11          comparison. I didn't see that kind of comparison.

12          So, anyway, I understand where it came  
13          from. I understand following the recipe. I  
14          understand all of that. But in that sense, there is  
15          no adjustment for that covariate except for these  
16          tables.

17          MR. MAISLIN: Right. The one mitigating  
18          factor, just if I can respond, -- and I have the  
19          tables from a preliminary manuscript. So it doesn't  
20          line up. But it's the same tables.

21          The proportion with good or excellent in  
22          those 14 PCL sparing and 5 was 92.1 percent and 85.5.

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1       There was a little bit less. And the revision rate  
2       was 5.6 vs. 9.2, 14 studies vs. 5 studies.

3               Let me just point out that those two  
4       studies that were identified as obsolete, one was in  
5       the 5 and one was in the 14. So that there is more  
6       weight to the bad studies in the PCL sacrificing.

7               MEMBER LARNTZ: Thank you.

8               CHAIRPERSON YASZEMSKI: Thanks, Mr.  
9       Maislin.

10              Dr. Walker, please? Briefly, please.

11              DR. WALKER: I'll be very brief. Just a  
12       brief comment, particularly to Dr. Mayor's comment  
13       about tests being monolithic and the words apply to  
14       all devices.

15              Yes. I think we should not lose sight of  
16       the fact that tests if they are any good should be  
17       able to distinguish between different kinds of  
18       devices. I mean, if we just restrict ourselves to one  
19       that we know they work, then the testing won't tell us  
20       much extra.

21              The purpose of the test, in fact, is to  
22       separate the sheep from the goats, if you like. It is

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1 to identify designs which do not perform  
2 satisfactorily.

3 So in that sense, I am somewhat  
4 comfortable about testing different kinds of designs  
5 because I believe their deficiencies will be revealed  
6 in the tests as in the special control guidance  
7 document.

8 CHAIRPERSON YASZEMSKI: Right. Thank you,  
9 sir.

10 Dr. Besser?

11 MEMBER BESSER: A certain part of the  
12 discussion so far seems to be concerned with whether  
13 the success rate of the mobile bearing knees is the  
14 same or different than the success rate of the fixed  
15 bearing knees. That is really I don't think the  
16 question that is in front of us.

17 I think, even if they are equal, the  
18 question is whether we can decide whether we can  
19 control manufacture of or designs of mobile bearing  
20 knees using special controls, as opposed to going  
21 through the PMA process.

22 A lot of the data that has been presented

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1 seems to be on, one, the LCS knee. I am reminded of  
2 the old Audi commercial that was very proud that 8 of  
3 10 Audis that were on the road 15 years ago were still  
4 on the road; whereas, 9 of those 10 Audis had been  
5 sold in the last 5 years because Audis had just been  
6 introduced in the U.S. market at the time.

7 I think that we can come up with special  
8 controls that would address wear aspects for different  
9 configurations of a mobile bearing knee. As long as  
10 special controls can be written, if you'll allow me,  
11 vaguely enough that we would like to address motion,  
12 multi-access motions, in all directions possible given  
13 a specific design, I think that can address the wear  
14 issues for a rotating vs. rotating and translating  
15 design. I don't think that's a problem.

16 And I imagine that for all of these from  
17 the standpoint of a mechanical engineer, we can test  
18 the heck out of them and definitely eliminate some  
19 that are destined to fail. However, there will be new  
20 and interesting manners of failure for any innovative  
21 design that won't be discovered until after they are  
22 implanted, unfortunately.

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1 CHAIRPERSON YASZEMSKI: Thank you, Dr.  
2 Besser.

3 Ms. Maher?

4 MEMBER MAHER: I actually don't have much  
5 to say on your first question. However, I just want  
6 to remind the panel that we are looking at the devices  
7 that are currently on the market. And the FDA has a  
8 strong skill set at looking at a 510K and determining  
9 whether something is substantially equivalent or  
10 whether the new changes and nuances of it fall and  
11 kick it over into the class III product. And that is  
12 something that Celia and her group, Dr. Witten and her  
13 group, have a very strong skill set at doing. So we  
14 need to look at the data we have now and make  
15 determinations.

16 CHAIRPERSON YASZEMSKI: Thanks, Ms. Maher.  
17 I will emphasize that point that if we recommend a  
18 general down classification of mobile bearing knees,  
19 the decision still has to be made in each individual  
20 application by the FDA as to whether the product that  
21 is being considered is substantially equivalent and  
22 falls into that general class II classification.

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1 Thank you for that clarification.

2 Dr. Doyle?

3 MEMBER DOYLE: I guess I am filtering all  
4 of the scientific evidence that has been offered here  
5 through my personal consumer looking forward to  
6 possibly having knee operations.

7 I think the thing that concerns me the  
8 most is basically no, I don't think all of the devices  
9 are alike because otherwise they wouldn't have  
10 designed them. I think each design is different to  
11 hopefully have some sort of improvements. The  
12 question I think is whether they are similar enough.

13 I think what bothered me was talking about  
14 the Oxford device that we don't have any special  
15 controls that would have picked up a device, if I  
16 understood correctly, that was not, that basically did  
17 have a rather large fault.

18 So looking down the road, I am a little  
19 concerned. And I do think that they are different  
20 enough that they may have to be considered separately,  
21 even those that have been looked at and even with the  
22 constraints that are available.

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1 CHAIRPERSON YASZEMSKI: Right. Thank you,  
2 Dr. Doyle.

3 We have had a rather thorough discussion  
4 in this preliminary phase prior to looking at the  
5 questions. So we are going to go to the questions  
6 now. I will ask that we consider each question  
7 independently and try to not redo all of the things we  
8 have done but to add any new information.

9 Having said that, I want everybody to have  
10 an opportunity to say what they think about the  
11 questions. We will start with question number one.  
12 Mr. Melkerson, can you put question number one up? We  
13 will read question number one. I will start with Dr.  
14 Kim on question number one, and we will come clockwise  
15 to Dr. Naidu next.

16 Question number one is, do you believe the  
17 proposed classification definitions for the following  
18 device configurations recommended for reclassification  
19 adequately describe the devices? If not, what changes  
20 in the definitions do you recommend for both total  
21 mobile bearing knee prostheses and unicompartmental  
22 mobile bearing knee prostheses? Dr. Kim?

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1 Does anyone want the description?  
2 Remember, Mr. Allen put those descriptions up. If  
3 anybody would like them, Dr. Witten will pass them  
4 around. Identify yourself and ask for them.

5 MEMBER KIM: The definition that was  
6 proposed is broad for both the total and the  
7 unicompartmental knees. Thus, it allows for a wide  
8 range of design features. This is obviously desirable  
9 if one wants to foster innovation. However, it makes  
10 the testing and implementation of special controls  
11 much more difficult.

12 So I don't have an exact answer for this  
13 question. I have more of a question for the question,  
14 which is that an acceptable definition will depend on  
15 our ability to have adequate special controls to test  
16 the wide variety of design features that would be  
17 allowed under this current definition.

18 My gut feeling is that with some effort,  
19 we could adopt those special controls. And I don't  
20 see any advantage in subcategorizing the various  
21 design features.

22 One change that I would recommend,

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1 according to what was stated previously by one of the  
2 panel members, that the patellar device was not  
3 adequately described. We need to address that issue  
4 in the definition.

5 CHAIRPERSON YASZEMSKI: Thanks, Dr. Kim.  
6 Dr. Naidu?

7 MEMBER NAIDU: Yes. I think the  
8 definitions are broad enough and all-inclusive, and I  
9 think they do adequately describe for both the total  
10 and the uni knees.

11 CHAIRPERSON YASZEMSKI: Thanks, Dr. Naidu.  
12 Dr. Mayor, your thoughts on question  
13 number one?

14 MEMBER MAYOR: Basically consistent with  
15 what I mentioned earlier in my earlier remarks, that  
16 the issue of wording regarding joint linkage and the  
17 issue of patellar design, being with or without mobile  
18 bearing.

19 CHAIRPERSON YASZEMSKI: Thanks, Dr. Mayor.  
20 Dr. Larntz?

21 MEMBER LARNTZ: I think definitions are  
22 fine with the change Dr. Mayor said.

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1 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
2 Larntz.  
3 Dr. Besser?  
4 MEMBER BESSER: Nothing to add.  
5 CHAIRPERSON YASZEMSKI: Thank you, Dr.  
6 Besser.  
7 Ms. Maher?  
8 MEMBER MAHER: Nothing to add.  
9 CHAIRPERSON YASZEMSKI: Thank you.  
10 Dr. Doyle?  
11 MEMBER DOYLE: Nothing to add.  
12 CHAIRPERSON YASZEMSKI: Thank you.  
13 Dr. Kirkpatrick?  
14 MEMBER KIRKPATRICK: Nothing to add.  
15 CHAIRPERSON YASZEMSKI: Thank you.  
16 Dr. Mabrey?  
17 MEMBER MABREY: Nothing to add.  
18 CHAIRPERSON YASZEMSKI: Thank you.  
19 Dr. Finnegan?  
20 MEMBER FINNEGAN: Nothing to add.  
21 CHAIRPERSON YASZEMSKI: Thank you.  
22 Dr. Witten, the panel has considered

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1 question number one. In general, they feel that the  
2 definitions are broad and cover the devices that may  
3 come under this classification.

4 There were a few concerns. They included  
5 the fact that the patellar device needs more  
6 clarification with the wording referring to whether it  
7 is mobile or not and additional wording regarding  
8 joint loading.

9 Have we adequately discussed this to FDA's  
10 satisfaction?

11 DR. WITTEN: Yes. Thank you.

12 CHAIRPERSON YASZEMSKI: You're very  
13 welcome

14 Question two, Mr. Melkerson? Question  
15 two, do you believe the risks to health of the  
16 following device configurations proposed for  
17 reclassification are adequately described? If not,  
18 what additional risks do you believe should be  
19 included for both the total mobile bearing and  
20 unicompartmental? Let's start with Dr. Finnegan this  
21 time.

22 MEMBER FINNEGAN: I'm going to actually

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1 break this down into three parts. I believe that the  
2 total bearing knee prosthesis, which is  
3 unidirectional, in fact, has been adequately described  
4 and the risks to health have been adequately  
5 described.

6 The second part I would like to say is  
7 that the multidirectional total bearing knee  
8 prosthesis I believe has been relatively  
9 well-described. I think that there are, as has been  
10 voiced, some risks to health that probably need to be  
11 looked at in some extra special controls.

12 My caveat for both of those is that I have  
13 a feeling that the patellar sacrificing may have some  
14 problems that have not been addressed by anyone. And  
15 I do think that probably needs to be either looked at  
16 through the literature cases and/or looked at in the  
17 lab.

18 And the third component is  
19 unicompartmental mobile bearing knee prosthesis. I do  
20 not think that the risks to health have been  
21 adequately described. The PMA is very young for the  
22 most recent ones. The indications for that one are

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1 significantly different from the one that has been on  
2 the market for a long time.

3 The revision rates are high, as one would  
4 expect. And I think there is not enough literature.  
5 There is not enough long-term follow-up. And I  
6 believe that that should be looked at separately.

7 Thank you.

8 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
9 Finnegan. May I ask for one point of clarification?  
10 You said the "patellar sacrificing" were a special  
11 case. Did you mean patellar sacrificing?

12 MEMBER FINNEGAN: I'm sorry. PCL  
13 sacrificing.

14 CHAIRPERSON YASZEMSKI: PCL sacrificing?

15 MEMBER FINNEGAN: Yes.

16 CHAIRPERSON YASZEMSKI: Thank you.

17 Dr. Kim?

18 MEMBER KIM: I have nothing to add to Dr.  
19 Finnegan's comments.

20 CHAIRPERSON YASZEMSKI: Thanks, Dr. Kim.  
21 Dr. Naidu?

22 MEMBER NAIDU: Nothing to add.

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1 CHAIRPERSON YASZEMSKI: Thank you.

2 Dr. Mayor?

3 MEMBER MAYOR: The only other issue that  
4 I think needs to be identified is that there are  
5 actually three classes of knee replacement that have  
6 been spoken of in the literature and in common  
7 practice: PCL retaining, PCL sacrificing, and PCL  
8 substituting.

9 While I can't cite the statistical basis  
10 on which the impression exists, in my own mind I think  
11 there are some differences between those devices which  
12 are truly PCL sacrificing, which the design may not  
13 address the question of what the PCL function is  
14 supposed to be, and designs which actually provide PCL  
15 substitution.

16 Otherwise no additional items to add.

17 CHAIRPERSON YASZEMSKI: Thank you, Dr.  
18 Mayor.

19 Dr. Larntz?

20 MEMBER LARNTZ: Nothing to add.

21 CHAIRPERSON YASZEMSKI: Thank you.

22 Dr. Besser?

1 MEMBER BESSER: Nothing to add.

2 CHAIRPERSON YASZEMSKI: Thank you.

3 Ms. Maher?

4 MEMBER MAHER: Nothing to add.

5 CHAIRPERSON YASZEMSKI: Thank you.

6 Dr. Doyle?

7 MEMBER DOYLE: Nothing to add.

8 CHAIRPERSON YASZEMSKI: Thank you.

9 Dr. Kirkpatrick?

10 MEMBER KIRKPATRICK: I agree with what has

11 been said so far.

12 CHAIRPERSON YASZEMSKI: Thank you.

13 Dr. Mabrey?

14 MEMBER MABREY: Nothing to add.

15 CHAIRPERSON YASZEMSKI: Thank you.

16 Dr. Witten, the panel has considered

17 question number two. They feel that in general, the

18 completeness of the risks to health with respect to

19 unidirectional mobile total bearing knees are okay;

20 that the multidirectional case perhaps needs

21 additional special controls, which has been a subject

22 of the discussion up to this point; that perhaps

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1 unicompartmentals may need to be separated out and  
2 needs further consideration before being included with  
3 all mobile bearing knees.

4 Have we adequately discussed this?

5 DR. WITTEN: Yes.

6 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
7 Witten.

8 Let's move on to question number three.  
9 Question number three, special controls have been  
10 proposed to address the risks to health identified in  
11 each of the above device configurations and all  
12 related sub-configurations. Please respond to the  
13 following questions regarding specific risks and/or  
14 specific controls. And there are several subparts.

15 A) Dislocation and subluxation of mobile  
16 bearing components have been cited as common  
17 complications in the literature. Do you believe  
18 appropriate special controls have been identified to  
19 adequately address these risks? And if not, what  
20 additional controls would you recommend?

21 Subpart B) A reduction in wear is often  
22 cited as a theoretical advantage of mobile bearing

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1 knees over fixed bearing devices. However, this has  
2 not been consistently demonstrated clinically, and it  
3 is not clear how well preclinical wear testing of  
4 mobile bearing knees correlates to the clinical  
5 situation.

6 In addition, the potential for third body  
7 wear appears greater and the potential for the amount  
8 of third body wear also appears to be greater.  
9 Currently, the state of development of knee simulator  
10 wear testing has not yet been standardized or  
11 clinically validated across all device types and,  
12 therefore, may not be applicable for all of the  
13 various mobile bearing knee types identified in the  
14 petition.

15 In light of the fact that wear appears to  
16 be, in part, design-dependent, do you believe  
17 appropriate controls have been identified to  
18 adequately address the risk of wear for the various  
19 mobile bearing knee designs under consideration? If  
20 not, what additional controls do you recommend?

21 Subpart C) Although labeling has been  
22 cited as a control with which to address risks to

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1 health, the proposed labeling requirements are  
2 consistent with those generally found in current fixed  
3 bearing total and unicompartmental knee package  
4 labeling. Labeling typically includes device  
5 description, type of material, indications for use,  
6 contraindications, adverse events, precautions,  
7 warnings, a listing of compatible components, and  
8 sterility information. What additional testing, if  
9 any, do you recommend for these mobile bearing knee  
10 components?

11 And part D) Do you believe appropriate  
12 special controls have been identified to adequately  
13 address the risks to health for each of the above  
14 device configurations and all sub-configurations? If  
15 not, what additional special controls do you  
16 recommend?

17 The summary of this is for each of parts  
18 A through D, do special controls exist? And if not,  
19 which ones need to be specified? Let's start with Dr.  
20 Mabrey.

21 MEMBER MABREY: Yes. Thank you.

22 I'll take those one at a time beginning

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1 with A, dislocation and subluxation of mobile bearing  
2 components have been cited as common complications in  
3 the literature.

4 I would contest that while these are the  
5 most common complications, they are not common  
6 complications. They occur infrequently. And those  
7 have been identified primarily as a result of errors  
8 in technique in many cases.

9 At this point, I believe that there are  
10 adequate controls to identify the inherent mechanical  
11 problems within the device itself to address the risk  
12 of dislocation of the mobile bearing.

13 With respect to B, a reduction in wear is  
14 often cited as a theoretical advantage, I agree at  
15 this point it is theoretical, although our ability to  
16 isolate wear debris and characterize it wear debris  
17 has improved significantly over the last few years.  
18 And I believe that those techniques are readily  
19 available to the sponsors and should be employed in  
20 the characterization of debris from their devices.

21 With regards to the different types of  
22 devices, unidirectional versus multidirectional, I

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1 think that should be an important component of the  
2 testing procedure looking at both unidirectional and  
3 multidirectional wear patterns within the knee.

4           Regarding labeling cited as a control  
5 addressing the risk to health and the proposed  
6 labeling requirements, I believe it's very difficult  
7 to legislate or regulate against incompetence.

8           We all know that these devices are  
9 technique-dependent. I think it is imperative that  
10 the implanting surgeon be familiar with the technique  
11 and familiar with total knee replacement before he or  
12 she even attempts that. I think the labeling and  
13 recommendations within the packaging are appropriate.

14           Finally, D) Do you believe appropriate  
15 special controls have been identified to adequately  
16 address the risks to health for each of the above  
17 device configurations and sub-configurations? And my  
18 answer to that would be yes based upon the special  
19 controls guidance document that we have been presented  
20 with and also based upon data presented here by the  
21 sponsors that those controls are available and  
22 appropriate.

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1 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
2 Mabrey.

3 Dr. Finnegan?

4 MEMBER FINNEGAN: I'm not going to add a  
5 whole lot more. I think for A, training probably  
6 recommended at least is a necessity. However, I do  
7 think in B -- and we had a wonderful presentation by  
8 Dr. Walker, but he kept sort of suggesting that maybe  
9 there are some new tests that need to be developed.  
10 And I think he is right for multidirectional wear,  
11 that probably there needs to be some work done and  
12 some new testing materials.

13 I don't have any comments on the labeling.  
14 And I think the risks to health we addressed in the  
15 previous question.

16 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
17 Finnegan.

18 Dr. Kim?

19 MEMBER KIM: I don't have any comments on  
20 A or C, but I want to echo the comments of Dr.  
21 Finnegan on B because it sounds like there are not  
22 adequate special control systems to test all of the

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1 different design configurations. Dr. Walker actually  
2 admitted that these exist in their minds but it's not  
3 on paper yet.

4 I would want some proof that a real  
5 adequate special control design can be formulated in  
6 this regard.

7 CHAIRPERSON YASZEMSKI: Thanks, Dr. Kim?  
8 Dr. Naidu?

9 MEMBER NAIDU: Nothing to add.

10 CHAIRPERSON YASZEMSKI: Thank you.  
11 Dr. Mayor?

12 MEMBER MAYOR: I would simply cite the  
13 earlier observations I made in my previous comments  
14 and also add that while the goal of absence of risk is  
15 unattainable, I think we can achieve a desirable  
16 reduction of risk.

17 The other observation is to identify the  
18 experience that we have had with standards applicable  
19 to materials that both the ISO and the ASTM standards,  
20 where materials are standardized, set a floor below  
21 which these materials should not fall without  
22 achieving what may be an even more desirable goal of

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1 identifying materials' qualities that may result in  
2 optimal performance. I think that is an important  
3 issue to bear in mind.

4 CHAIRPERSON YASZEMSKI: Thanks, Dr. Mayor.  
5 Dr. Larntz?

6 MEMBER LARNTZ: Well, I'm not sure how to  
7 address the individual questions. I will just say  
8 that I think that from what I can see and the  
9 variation in devices, the variation results, it is  
10 going to be very difficult for me to think that we  
11 could adequately address issues for these devices  
12 without implantation.

13 I think that we are going to have to have  
14 a clinical study. I realize clinical studies can be  
15 part of special controls, but I don't think they were  
16 mentioned in the special controls proposed.

17 I do believe that a clinical study is  
18 going to be necessary for new designs because I think  
19 it is just going to be impossible given the way we  
20 have seen. I mean, the history is such that I just  
21 can't imagine without a clinical study with some  
22 reasonable follow-up time.

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1           Typically I think that would stay as a  
2 class III and go into it under an IDE. But I realize  
3 you can do clinical studies and require them as part  
4 of this process. So if a special control could be put  
5 together that included a clinical study, then I would  
6 guess that is what I would do.

7           I think the mechanical, preclinical, all  
8 of that testing seems to be amazingly good but unable  
9 to identify what happens until in final implantation.

10           Thank you.

11           CHAIRPERSON YASZEMSKI:       Thanks, Dr.  
12 Larntz.

13           Dr. Besser?

14           MEMBER BESSER: I would echo Dr. Larntz's  
15 comments. I had been working with the assumption that  
16 there would be clinical trials for these. However,  
17 that is not part of the class II requirements. So  
18 yes, I do believe that, in fact, the  
19 dislocation/subluxation where can be handled by  
20 special controls, the special controls that are  
21 currently in place. Plus, I would add some language  
22 for the wear that would require multiple modes of

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1 motion to be tested for wear at the same time.

2 Don't do three separate tests, one for  
3 translation, one for rotation, one for translation,  
4 and another access, but to combine those during wear  
5 testing and definitely would require clinical data  
6 before approving device for market.

7 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
8 Besser.

9 Ms. Maher?

10 MEMBER MAHER: I would follow up with what  
11 Dr. Besser said. I think the correct term would be  
12 510k's may require clinical data, as opposed to a  
13 clinical study, to allow the FDA and the sponsor of  
14 the 510k's to determine what would be adequate if that  
15 is what we are doing.

16 CHAIRPERSON YASZEMSKI: Thank you.

17 Dr. Doyle?

18 MEMBER DOYLE: I agree with everything  
19 that has been said, particularly the emphasis on  
20 clinical data, because I think studying something  
21 under laboratory conditions that are ideal is very  
22 different from seeing how it works in a 250-pound man

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1 who is clumsy.

2 CHAIRPERSON YASZEMSKI: Thank you, Dr.  
3 Doyle.

4 Dr. Kirkpatrick?

5 MEMBER KIRKPATRICK: I agree with Dr.  
6 Finnegan on A that training is essential. I think  
7 special controls could be involved by adding it to C,  
8 which is labeling; in other words, restricting it to  
9 people who have been adequately trained if it is a  
10 device that is that specific, as we have heard that  
11 several are.

12 I would also suggest that another control  
13 on the training and insurance of adequate technique  
14 can be restriction of the device to people that have  
15 been trained, as we heard yesterday. I think that  
16 would be another option for the FDA to negotiate with  
17 the companies on, a special control for that.

18 As far as reduction in wear, I think that  
19 we can establish special controls that can apply. As  
20 we heard, there may be or there is a concept of a  
21 joint simulator test, which might pick up some of  
22 these things. If that is developed, obviously I think

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1 FDA would automatically include that in their  
2 analysis.

3 In the absence of that, I think a  
4 post-market analysis of dislocations of wear and of  
5 any retrievals possible, although we can't mandate the  
6 companies to get all of those retrievals, we can  
7 certainly ask them to keep a very close eye on what is  
8 published and any concerns that come into them so that  
9 they can give that feedback as well.

10 I also think on D that I agree with Dr.  
11 Finnegan that it sounds like we need to separate out  
12 the unicondylars in the totals as different devices.

13 Thank you.

14 CHAIRPERSON YASZEMSKI: Thank you, Dr.  
15 Kirkpatrick

16 Dr. Witten, may I ask you for  
17 clarification from the FDA regarding clinical data in  
18 class II devices because several members commented on  
19 that and seemed to express some uncertainty about the  
20 relationship?

21 DR. WITTEN: Yes. Well, as was mentioned,  
22 it's not something that we would automatically request

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1 or expect to see in a 510k. But in evaluating the  
2 device and the testing and the comparison to the  
3 predicate device, which the sponsor would need to  
4 provide, it could be that there would be a question  
5 raised that we would suggest that clinical data be the  
6 mechanism to address that particular difference or  
7 issue.

8 CHAIRPERSON YASZEMSKI: Right. Thank you,  
9 Dr. Witten.

10 Have we adequately discussed question  
11 three?

12 DR. WITTEN: Yes, you have.

13 CHAIRPERSON YASZEMSKI: Thank you.

14 Question four, do you believe the data  
15 presented in this petition supports the  
16 reclassification of: A) all total mobile bearing  
17 knee prostheses identified in the petition? And if  
18 not, which types of total knees do you believe are  
19 inappropriate for reclassification and why? B) All  
20 unicompartmental mobile bearing knee prostheses  
21 identified in the petition? And if not, which types  
22 do you believe are inappropriate for reclassification

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1 and why? I would like to start with Dr. Mayor this  
2 time.

3 MEMBER MAYOR: Thank you.

4 Yes. I think, as I have implied in my  
5 previous remarks, I think the data has been presented  
6 to support the reclassification of both the  
7 bicompartmental, tricompartmental mobile bearing knees  
8 and the unicompartmentals in the same reclassification  
9 motion.

10 CHAIRPERSON YASZEMSKI: Thanks, Dr. Mayor.

11 Dr. Larntz?

12 MEMBER LARNTZ: While I agree clinical  
13 data can go in 510k's, it's not the usual thing. I  
14 think we do need clinical data. And I think that has  
15 to be the standard until we get more experience with  
16 these devices. And so I would be opposed to  
17 reclassification.

18 CHAIRPERSON YASZEMSKI: Thank you, Dr.  
19 Larntz.

20 Dr. Besser?

21 MEMBER BESSER: I believe that both the  
22 total and the unicompartmental devices, mobile bearing

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1 devices, could be reclassified as class II. However,  
2 I would agree with Dr. Larntz that clinical data is  
3 required. And I would list that as a special control.

4 CHAIRPERSON YASZEMSKI: Thank you, Dr.  
5 Besser.

6 Ms. Maher?

7 MEMBER MAHER: Nothing further to add.

8 CHAIRPERSON YASZEMSKI: Thank you.

9 Dr. Doyle?

10 MEMBER DOYLE: I concur with what has been  
11 said.

12 CHAIRPERSON YASZEMSKI: Thank you.

13 Dr. Kirkpatrick?

14 MEMBER KIRKPATRICK: I am most comfortable  
15 with the tricompartmental devices. I am a little  
16 concerned about unicompartmental devices. So I would  
17 say a yes on the first and a no on the second.

18 CHAIRPERSON YASZEMSKI: Thanks, Dr.  
19 Kirkpatrick.

20 Dr. Mabrey?

21 MEMBER MABREY: I have nothing to add.

22 CHAIRPERSON YASZEMSKI: Thank you.

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1 Dr. Finnegan?

2 MEMBER FINNEGAN: Yes on A and no on B.

3 CHAIRPERSON YASZEMSKI: Thank you.

4 Dr. Kim?

5 MEMBER KIM: I have nothing to add.

6 CHAIRPERSON YASZEMSKI: Thank you.

7 Dr. Naidu?

8 MEMBER NAIDU: No on both.

9 CHAIRPERSON YASZEMSKI: Thank you.

10 Dr. Witten, have we adequately discussed  
11 question four?

12 DR. WITTEN: Yes.

13 CHAIRPERSON YASZEMSKI: Thank you.

14 RECLASSIFICATION QUESTIONNAIRE AND  
15 SUPPLEMENTAL DATA SHEET, AND VOTE

16 CHAIRPERSON YASZEMSKI: Now that we have  
17 addressed the FDA questions, we will complete the  
18 classification questionnaire and supplemental data  
19 sheet. So our task now is to fill out two sheets.

20 Ms. Shulman of the Office of Device  
21 Evaluation will assist us. After panel discussion of  
22 each question, I will note our answer for each blank

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1 on the data sheet. And Ms. Shulman will record it on  
2 the overhead for us. What we will vote on is the  
3 completed questionnaire and data sheet. That vote  
4 will become the panel's recommendation to the FDA.

5 Does anyone have questions on how we are  
6 about to proceed? Can we get sheets for everybody,  
7 please? Once we distribute the sheets, I will note  
8 that Dr. Mayor was the lead reviewer. I am going to  
9 ask his guidance on how to proceed with the answers.

10 We will have discussion on each of the  
11 answers and recognize that if there is disagreement on  
12 the answers, we will fill the sheet out based upon our  
13 impression of what the majority consensus opinion is.  
14 And you can address disagreement, should you have it,  
15 with your vote when the sheets are completed. Does  
16 everybody have a copy now?

17 Let's start out with question one. Is the  
18 device life-sustaining or life-supporting? And, as  
19 you will note, questions one, two, and three, a yes  
20 answer in any of the questions one, two, and three  
21 makes us answer question four yes. And then we have  
22 to go to item six. If not, we go to item five. The

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1 decision point here is whether any of one, two, and  
2 three get a yes answer.

3 MEMBER FINNEGAN: Mr. Chair, a question.

4 CHAIRPERSON YASZEMSKI: Yes, ma'am.

5 MEMBER FINNEGAN: Maybe an objection. Why  
6 are we doing two of these together?

7 CHAIRPERSON YASZEMSKI: I think the way I  
8 am going to want to do this if there are no gross  
9 objections to it are to do them both together and see  
10 how the discussion proceeds and how the vote goes.  
11 And if the vote is negative for both of them together,  
12 we are going to redo it with both of them alone.  
13 Let's proceed that way if everybody will be okay with  
14 that. Then we will see how the discussion goes.

15 This first round will be considering both  
16 together, both totals and unis together. And I  
17 encourage everybody to state their opinion and then  
18 speak with their vote. Is the device -- and device  
19 now considers both of them: totals and unis --  
20 life-sustaining or life-supporting?

21 Dr. Mayor, since you are the lead  
22 reviewer, I am going to ask you to start the

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1 discussion on every one of the questions. Yes or no  
2 to item one?

3 MEMBER MAYOR: I think my understanding of  
4 the definition of life-sustaining and life-supporting,  
5 the answer to that question would be no.

6 CHAIRPERSON YASZEMSKI: I think with  
7 respect to this, are there any objections to no for  
8 question one?

9 (No response.)

10 CHAIRPERSON YASZEMSKI: We are going to go  
11 to question two. Is the device for a use which is of  
12 substantial importance in preventing impairment of  
13 human health? Dr. Mayor?

14 MEMBER MAYOR: Again, my understanding  
15 would be that the answer to that question would be  
16 yes.

17 CHAIRPERSON YASZEMSKI: Any objection to  
18 answering yes to question two?

19 (No response.)

20 CHAIRPERSON YASZEMSKI: Question three,  
21 does the device present a potential unreasonable risk  
22 of illness or injury?

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1                   MEMBER MAYOR: Again, in relationship to  
2 my understanding that risk-free is unattainable, I  
3 would answer no to that question.

4                   CHAIRPERSON YASZEMSKI: Are there  
5 objections for no to question three?

6                   (No response.)

7                   CHAIRPERSON YASZEMSKI: Question four, did  
8 you answer yes to any of the above? The answer to  
9 that is yes. So the effect of questions one, two, and  
10 three is --

11                   MEMBER KIM: Mr. Chairman, I'm sorry.

12                   CHAIRPERSON YASZEMSKI: Dr. Kim?

13                   MEMBER KIM: I do object. Sorry I didn't  
14 speak up earlier. I would say yes to question number  
15 three that there is a potential for unreasonable --

16                   CHAIRPERSON YASZEMSKI: Are there other  
17 suggestions?

18                   MEMBER FINNEGAN: I agree.

19                   CHAIRPERSON YASZEMSKI: Let's now vote on  
20 question three. Just a yes or no, and we are going to  
21 put in the majority. Dr. Kirkpatrick, question three,  
22 yes or no?

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1 MEMBER KIRKPATRICK: Can I just ask for  
2 them to tell us what unreasonable risks are not known?

3 CHAIRPERSON YASZEMSKI: Okay. One short  
4 question because we can all speak with our vote. Dr.  
5 Kim or Dr. Finnegan, do you want to say what the  
6 unreasonable risks are?

7 MEMBER KIM: I don't have in my mind  
8 assurance that the various designs may fail. Well,  
9 let me ask a clarification question. When it says  
10 "the device," does it mean the predicate device that  
11 exists right now --

12 CHAIRPERSON YASZEMSKI: Talking about the  
13 devices under consideration for reclassification.

14 MEMBER KIM: -- or the definition that  
15 we're looking at?

16 CHAIRPERSON YASZEMSKI: The definition  
17 that we are considering now.

18 MEMBER FINNEGAN: My understanding was  
19 that all class III's are a yes for that answer. And  
20 these are presently all class III's.

21 CHAIRPERSON YASZEMSKI: We don't have to  
22 consider that now. It is our decision whether to say

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1 that the device is under consideration because we are  
2 going to vote whether to make the devices under  
3 consideration III or II today. So we have to answer  
4 what we feel today without regard to previous  
5 classification of these devices.

6 So let's speak with our vote. Dr.  
7 Kirkpatrick? Question three, yes or no?

8 MEMBER KIRKPATRICK: No.

9 CHAIRPERSON YASZEMSKI: Dr. Mabrey?

10 MEMBER MABREY: No.

11 CHAIRPERSON YASZEMSKI: Dr. Finnegan?

12 MEMBER FINNEGAN: Yes.

13 CHAIRPERSON YASZEMSKI: Dr. Kim?

14 MEMBER KIM: Based on your clarification,  
15 I will vote no.

16 CHAIRPERSON YASZEMSKI: Dr. Naidu?

17 MEMBER NAIDU: Yes.

18 CHAIRPERSON YASZEMSKI: Dr. Mayor?

19 MEMBER MAYOR: No.

20 CHAIRPERSON YASZEMSKI: Dr. Larntz?

21 MEMBER LARNTZ: No.

22 CHAIRPERSON YASZEMSKI: Dr. Besser?

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1 MEMBER BESSER: No.

2 CHAIRPERSON YASZEMSKI: We will conclude  
3 an answer of no for question three. That makes the  
4 answer to question four yes. And we now go to item  
5 six.

6 Item six, is there sufficient information  
7 to establish special controls in addition to general  
8 controls to provide reasonable assurance of safety and  
9 effectiveness?

10 I think what I would like to suggest here  
11 is the way to get everybody's opinion on this is let's  
12 go around and vote. Dr. Mayor, yes or no?

13 MEMBER MAYOR: Yes.

14 CHAIRPERSON YASZEMSKI: Dr. Larntz?

15 MEMBER LARNTZ: No.

16 CHAIRPERSON YASZEMSKI: Dr. Besser?

17 MEMBER BESSER: Yes.

18 CHAIRPERSON YASZEMSKI: Dr. Kirkpatrick?

19 MEMBER KIRKPATRICK: As currently defined,  
20 I would have to say no.

21 CHAIRPERSON YASZEMSKI: Dr. Mabrey?

22 MEMBER MABREY: Yes.

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1 CHAIRPERSON YASZEMSKI: Dr. Finnegan?

2 MEMBER FINNEGAN: No.

3 CHAIRPERSON YASZEMSKI: Dr. Kim?

4 MEMBER KIM: No.

5 CHAIRPERSON YASZEMSKI: Dr. Naidu?

6 MEMBER NAIDU: No.

7 CHAIRPERSON YASZEMSKI: This is a five to  
8 three. Let's recast. I got five to three. Let me  
9 repoll. I got yes from Dr. Mayor. I got a no from  
10 Dr. Larntz. Dr. Besser? Just repeat your votes. I  
11 got a no from Dr. Besser or a yes?

12 MEMBER BESSER: Yes.

13 CHAIRPERSON YASZEMSKI: We have a  
14 discrepancy here. Ms. Scudiero had four to four, and  
15 I had five to three. So I am going to ask for a  
16 revote. Dr. Mayor?

17 MEMBER MAYOR: Yes.

18 CHAIRPERSON YASZEMSKI: Dr. Larntz?

19 MEMBER LARNTZ: No.

20 CHAIRPERSON YASZEMSKI: Dr. Besser?

21 MEMBER BESSER: Yes.

22 CHAIRPERSON YASZEMSKI: Dr. Kirkpatrick?

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1 MEMBER KIRKPATRICK: No.

2 CHAIRPERSON YASZEMSKI: Dr. Mabrey?

3 MEMBER MABREY: Yes.

4 CHAIRPERSON YASZEMSKI: Dr. Finnegan?

5 MEMBER FINNEGAN: No.

6 CHAIRPERSON YASZEMSKI: Dr. Kim?

7 MEMBER KIM: No.

8 CHAIRPERSON YASZEMSKI: Dr. Naidu?

9 MEMBER NAIDU: No.

10 CHAIRPERSON YASZEMSKI: I have five to  
11 three for no. The answer to question six is no. This  
12 would make it a class III. So at this point, we would  
13 vote on this device classification questionnaire as to  
14 whether we would vote to put the combined  
15 classification in class III.

16 So I will ask Ms. Shulman. Is that where  
17 we are at? Do we not need to fill out the  
18 supplemental data sheet if we are going to vote on  
19 whether it should be class III?

20 MS. SHULMAN: I have a question of  
21 clarification at this point because of some of the  
22 answers. Did you then want to decide if it should be

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1 split at this time?

2 CHAIRPERSON YASZEMSKI: What I'm going to  
3 say is that for this motion to include them both  
4 together, I want to vote. And if the vote is a no for  
5 class III, then I am going to ask for a second motion  
6 to split them.

7 So at this point, if we are voting on  
8 class III, do we need a supplemental data sheet or  
9 shall we simply vote?

10 MS. SHULMAN: No. Simply vote.

11 CHAIRPERSON YASZEMSKI: So we're going to  
12 vote. There is a classification recommendation based  
13 upon this sheet for class III. I am going to ask us  
14 to vote. Then I am going to ask for a reconsideration  
15 separating them.

16 So the vote that I am going to ask for --  
17 and I am going to start with you, Dr. Kirkpatrick --  
18 is for the petition as it stands to include all total  
19 knee, mobile total knees, and unidirectional total  
20 knees, together to keep them as a class III device.

21 If you vote yes, then this is a vote for  
22 keeping them together as class III's. We will

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1 subsequently then if that occurs separate it into  
2 separate petitions for class II's based upon totals  
3 and unis separately. As it stands, this is a vote for  
4 class III for the combined mobile bearing knees,  
5 totals and unis.

6 Dr. Kirkpatrick?

7 MEMBER KIRKPATRICK: Just as  
8 clarification, you said "unidirectional," but I think  
9 you meant unicondylar.

10 CHAIRPERSON YASZEMSKI: I meant  
11 unicondylar. Thank you.

12 MEMBER KIRKPATRICK: Or unicompartmental.  
13 Excuse me.

14 CHAIRPERSON YASZEMSKI: Unicompartmental.  
15 Yes, sir.

16 MEMBER KIRKPATRICK: Then I would vote for  
17 class III. Is that what you're asking?

18 CHAIRPERSON YASZEMSKI: Yes. Dr.  
19 Kirkpatrick, yes. Dr. Mabrey?

20 MEMBER MABREY: I vote against class III.

21 CHAIRPERSON YASZEMSKI: Thank you. Dr.  
22 Mabrey, no.

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