

TRANSCRIPT OF PROCEEDINGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

DENTAL PRODUCTS PANEL MEETING

OPEN SESSION - VOLUME II

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Pages 1 Thru 220

Rockville, Maryland
August 5, 1998

MILLER REPORTING COMPANY, INC.

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OPEN SESSION - VOLUME II

Wednesday, August 5, 1998

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Rockville, Maryland 20850

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P R O C E E D I N G S

MS. SCOTT: Good morning.

Welcome to our second day of the Dental Products Panel meeting. Again, my name is Pamela Scott, and I am the Executive Secretary for the Dental Products Panel.

If you have not signed in, please, do so at the sign-in desk just outside of the room. At the sign-in desk, again, you will find agenda booklets and other information pertaining to today's meeting. Also, you will find information on obtaining a transcript of today's meeting, if you are interested.

At this time I would, again, like to introduce our panel for today. Our Acting Chair for today is Dr. Janine Janosky, who is Associate Professor with the Department of Family Medicine and Clinical Epidemiology with the School of Medicine at the University of Pittsburgh.

We have our Consumer Representative, Dr. Altman, who is the Chief of the Office of Oral Health in the Arizona Department of Health Services.

Mr. Foyt Larson, who is the President of Pacific Materials and Interfaces. Dr. Peter Bertrand, who is the Director of the Orificial Pain Clinic at the National Naval Medical Center.

Dr. Richard Burton, who is Assistant Professor of Oral and Maxillofacial Surgery with the Department of

1 Hospital Dentistry at the University of Iowa Hospital and
2 Clinics. We have Dr. Gilbert Gonzales, who is Associate
3 Professor of Neurology at the Memorial Sloan-Kettering
4 Cancer Center at Cornell University.

5 Also, I will have, by speaker-phone, Dr. Leslie
6 Heffez, who is the Professor and Department Head of Oral and
7 Maxillofacial Surgery with the University of Illinois.

8 We have Dr. Allen Moses, who is a TMD and
9 Orificial Pain Specialist and on the Teaching Staff at
10 Michael Reese Hospital.

11 We have Dr. Robert Talley, who is also a TMD and
12 Orificial Pain Specialist. And we have Dr. Diane Rekow, who
13 is the Chairperson of the Department of Orthodontics with
14 the University of Medicine and Dentistry of New Jersey.

15 And, also, I would like to introduce our Acting
16 Division Director, Dr. Steven Gutman, and he is Acting
17 Division Director for the Division of Dental Infection
18 Control and General Hospital Devices. I do apologize for
19 not introducing him formally yesterday.

20 At this time, I need to read our conflict of
21 interest statement for today.

22 "August 5th, 1998, Conflict of Interest Statement.
23 The following announcement addresses conflict of interest
24 issues associated with this meeting and is made part of the
25 record to preclude even the appearance of an impropriety.

1 "The conflict of interest statutes prohibit
2 special government employees from participating in matters
3 that could affect their or their employer's financial
4 interest. To determine if any conflict existed, the agency
5 reviewed the submitted agenda and all financial interests
6 reported by the committee participants. The agency has no
7 conflicts to report.

8 "In the event that the discussions involve any
9 other products or firms not already on the agenda for which
10 an FDA participant has a financial interest, the participant
11 should excuse him or herself from such involvement and the
12 exclusion will be noted for the record. With respect to all
13 other participants we ask, in the interest of fairness, that
14 all persons making statements or presentations disclose any
15 current or previous financial involvement with any firm
16 whose products they may wish to comment upon."

17 I would also, again, like to read into the record
18 the appointment of temporary voting status. "Pursuant to
19 the authority granted under the Medical Devices Advisory
20 Committee Charter, dated October 27, 1990, and as amended on
21 October 20, 1995, I appoint the following people as voting
22 members of the Dental Products Panel for this meeting on
23 August 4th through the 5th, 1998: Dr. Peter Bertrand, Dr.
24 Richard Burton, Dr. Gilbert Gonzales, Dr. Leslie Heffez, Dr.
25 Allen Moses, Dr. Diane Rekow, and Dr. Robert Talley. For

1 the record, these people are special government employees
2 and are consultants to this panel under the Medical Devices
3 Advisory Committee.

4 "I also appoint Dr. Janine Janosky to act as
5 temporary Chairperson for the duration of the Dental
6 Products Panel meeting. For the record, Dr. Janosky is a
7 special government employee and is a voting member of the
8 Dental Products Panel. The above individuals have undergone
9 the customary conflict of interest review. They have
10 reviewed the material to be consider at this meeting, signed
11 by Dr. Bruce Burlington, Director for the Center of Devices
12 and Radiological Health, July 31, 1998."

13 At this time, I will turn the meeting over to Dr.
14 Janosky.

15 CHAIRPERSON JANOSKY: Thank you.

16 Today we will continue our discussion and make a
17 recommendation to the Food and Drug Administration regarding
18 the classification of sonographic devices and jaw tracking
19 devices.

20 At this time, we open the floor to anyone from the
21 public who would like to address the panel.

22 We do have a request for one of the speakers who
23 would like to speak in the last position. So, is there
24 anyone else who would like to speak during this open public
25 hearing?

1 Would you, please, go to the microphone.

2 Are you Dr. Barry Cooper?

3 DR. COOPER: Yes, I am.

4 CHAIRPERSON JANOSKY: Can I see if there is anyone
5 else at this time?

6 . Is there anyone else who would like to address the
7 panel at this time?

8 I have a list of six individuals who have
9 requested. I am actually asking for anyone who is not on
10 this list.

11 [No response.]

12 CHAIRPERSON JANOSKY: Okay. Then we will proceed
13 with this list.

14 The order that I have is Dr. Barry Cooper, Dr.
15 Roland Jankelson, Dr. Gary Wolford, Dr. Larry Tilley, Dr.
16 Robert Jankelson and Ms. Terrie Cowley.

17 Given the time, each of the speakers will have
18 five minutes with questions from the panel, if there are
19 any.

20 Okay. So, no other requests?

21 [No response.]

22 CHAIRPERSON JANOSKY: Then we will proceed.

23 Dr. Barry Cooper.

24 DR. COOPER: Thank you. I will be very brief. I
25 first of all, wanted to thank the panel and the FDA for

1 giving me the opportunity of participating in these last two
2 days' events and for allowing us to not only make a formal
3 presentation but to comment on the proceedings as they go
4 on.

5 Just briefly, since we have demonstrated that jaw
6 tracking and sonography are measurement devices, I would
7 like to recommend that they be classified as class I.

8 Thank you.

9 CHAIRPERSON JANOSKY: Are there any questions from
10 any of the panel members?

11 [No response.]

12 CHAIRPERSON JANOSKY: If not, Mr. Roland
13 Jankelson.

14 MR. JANKELSON: Good morning.

15 I, too, would like to thank the panel for their
16 service and for the opportunity of making comments yesterday
17 and briefly this morning.

18 The issue I wanted to deal with very quickly this
19 morning was on the matter of sonography. I think that the
20 point that I want to emphasize is that with respect to
21 sonography, there really are two devices. One is a
22 recording device. The second one can be something more than
23 a recording device. If that device makes claims that it
24 interprets the information recorded in a fashion that
25 independently a diagnosis for the doctor, that device

1 becomes something more than a recording device.

2 I would like to read since it is, I think,
3 essentially one sentence, the claim that is made for the
4 Myotronics device from our current 510(k).

5 "The electrosonogram, ESG-1, is a non-invasive
6 device that measures and records sounds emitted from the
7 temporomandibular (jaw) joint along with the relative
8 position of the jaw as a means of assessing the status of
9 the temporomandibular joints."

10 The point I'm making is that the claim that we
11 make for our sonography device is that it records. It does
12 not interpret, it does not analyze for the doctor, it does
13 not diagnose for the doctor.

14 If there are any questions, I would be happy to
15 answer them. Otherwise, that would conclude my comments.

16 DR. BURTON: My only concern is the fact that I've
17 been at numerous professional meetings over the last several
18 years and it is not, Gil, just certainly with your company
19 but also other vendors. There are obviously other units on
20 the market.

21 But I've heard claims candidly made by sales
22 personnel at these meetings that go beyond that kind of
23 statement and I think that's is probably the biggest concern
24 that I have is not--and I would agree with the statements
25 made by several of you about the fact that these are

1 measurement devices. However, I think that what I have seen
2 marketed to the dental profession on many occasions have
3 been claims and statements made beyond that level.

4 And I know that is something that you can't always
5 control. But that is where I think a lot of the difficulty
6 arises is that I have personally heard and seen that and I'm
7 not talking just about your company.

8 MR. JANKELSON: To the contrary though. It is
9 something that not only can a manufacturer control; it is
10 something that the manufacturer is legally obligated to
11 control, under existing regulation. Information
12 disseminated in an educational seminar is part of our label.

13 And the FDA is extremely aware of what those
14 claims are. And if those claims expand beyond the 510(k)
15 then that manufacturer is violating the law. I don't want
16 to expand this, but can I ask you, have you heard that
17 expansion of that claim in any way connected with any
18 educational activity in which Myotronics was associated or
19 involved?

20 DR. BURTON: Personally, no. I've heard
21 colleagues who made statements to that effect but that's
22 obvious that's all hearsay. So, it might not.

23 MR. JANKELSON: I can tell you since I've been
24 around Dr. Robert Jankelson--and I am not a doctor--since I
25 was born, since we're twins. And he has had a very defined

1 position on the state of the science with respect to
2 sonography and it's been our company's position that we do
3 not make claims with respect to independent diagnosis.

4 and nobody associated with any educational process
5 or sales process has the authority to expand the claim
6 beyond the specific claim in our 510(k). They're told that,
7 and, I mean we respect our obligations with respect to what
8 labeling we can put on our devices. And anything that we
9 say is part of that label.

10 DR. BURTON: Thank you.

11 CHAIRPERSON JANOSKY: Additional questions?

12 [No response.]

13 CHAIRPERSON JANOSKY: Mr. Jankelson, I know that
14 you had told us yesterday but would you, please, tell us
15 again, the affiliation?

16 MR. JANKELSON: Yes, certainly. I am associated
17 with Myotronics.

18 Thank you.

19 CHAIRPERSON JANOSKY: Financial interests?

20 MR. JANKELSON: Yes.

21 CHAIRPERSON JANOSKY: Myotronics?

22 MR. JANKELSON: Yes, yes.

23 CHAIRPERSON JANOSKY: Okay.

24 Am I correct in Dr. Gary Wolford, you decline?

25 Okay.

1 Dr. Larry Tilley?

2 Please state your name and affiliation and any
3 financial interests

4 DR. TILLEY: Thank you.

5 I am Larry Tilley. I am Chairman of the American
6 Alliance of TMD Organizations and I'm in private practice.
7 I have no financial affiliation or financial entanglement
8 with the two organizations, although I have lectured for
9 both of them in the past.

10 The American Alliance of TMD Organizations is made
11 up of 10 organizations now that totals over 10,000
12 practitioners or represents over 10,000 practitioners. And
13 we are brought together, as Ms. Cowley said, because of the
14 difficulties that we had in TMD. The reality of it though
15 is a lot more than financial; it goes back to the 1986 draft
16 status report and the NIH Conference which basically said
17 that the only thing that was of any real value was cognitive
18 behavioral therapy and EMG biofeedback. And we felt very
19 strongly that that was something that our patients weren't
20 going to benefit from. So, that's the reason we came
21 together.

22 The concern over the draft status report was
23 focused on the instrumentation but it was much broader than
24 that, at least we felt like at the time. And it was widely
25 distributed, as someone said yesterday, not after the

1 meeting but before the meeting even took place. It was
2 classified or marked on it, draft only not to be referenced,
3 and was used already for denials of insurance claims.

4 As I reported at the last meeting, that was
5 reproduced in its entirety in the journal, Prostate
6 Dentistry, even though it was, indeed, rejected by the
7 committee.

8 Ms. Cowley also pointed out yesterday about the
9 money joint and I've heard that, too, and maybe it is for
10 people who that is the mainstay of their practice, that is
11 the only thing they do. But for the average practitioner
12 out there it, in fact, is not very profitable. It would be
13 better off to put that out of your practice and continue to
14 do general dentistry or implants or something and, in fact,
15 many people have done that. Fewer and fewer people are
16 entering the field.

17 In a letter from the Neuro Science Group of the
18 IADR to the Neuro Science Group members and to the American
19 University Teachers of Orificial Pain Practices, TMD
20 practitioners were accused of questioning the ADA, FDA and
21 NIH activities based on money and conviction. I don't know
22 that it was--we have already talked about the money--but the
23 conviction is really the big thing, I think.

24 We've addressed money and we certainly have seen
25 improprieties. We have seen TMJ cases with my personal--I

1 had a personal case that was treated by a "neuro-muscular
2 doctor" if you want to call him that and the totals were
3 about \$37,000, which included some orthoscopic surgery.

4 I have seen thousands of dollars worth of
5 radiographs and been on a committee to deal with that in
6 Georgia. And in Reader's Digest even had a thing a year or
7 so ago, I guess, about the \$700-case that went around the
8 country and needed as much as \$20,000 worth of dentistry
9 according to someone.

10 So, you know, it's not about the instrumentation
11 or the instrument; it's about the morality of the
12 individuals and we're not going to be able to legislate
13 that.

14 The Alliance has questioned a significant amount
15 of NIH funding because much of the research has been in
16 psycho-social research and the clinical academicians around
17 the country complained that they have a very difficult time
18 getting research funding, big name researchers, and I will
19 be glad to share any of that with you, if you would like.

20 One of our member organizations has taken hold of
21 that. Barry mentioned the difficulty of getting funding.
22 And, so, one of our organizations, the American Academy of
23 Head and Neck Facial Pain, has taken on themselves to do a
24 research study using the TMJ scale. And they've also
25 offered a fellowship, mastership, diplomate, ways to insist

1 that their membership progress education-wise.

2 Research shows that interrelated reliability and
3 palpation and joint sounds is as little as 50 percent and
4 all protocols of all the organizations want to look at jaw
5 motion, range of motion, clicking, where it occurs, and they
6 recommend grafting it. And there's no way to graft it
7 better than jaw tracking.

8 You know, does the machine show the jaw moves
9 forward and back and sideways and record the click at the
10 proper vertical and things like that?

11 But yesterday was focused on philosophy not
12 instrumentation. And we are never going to solve that
13 problem. The Alliance certainly has no ability to make the
14 philosophy all one, although that would be nice. So, that's
15 something that you're not going to solve either.

16 I've practiced very differently than Dr. Cooper.
17 I address internal derangement. I'm a massage therapist,
18 so, I look at upper quarter problems, I look at posture.
19 And what is significant though is does the instrument do
20 what it says it does as far as recording? It's not the
21 philosophy. The philosophy is a battle that we're never
22 going to be able to deal with. Is it safe, is it effective?

23 The significance of the committee activities is
24 enlarged by the history of all of this uproar that has gone
25 on and the emotion of the topic. But the most important

1 thing for this committee is to take a diligent, thoughtful
2 and measured approach as you view the issues and stay with
3 the issue of safety and efficacy.

4 And the Alliance commits to you and to anyone else
5 that will listen to the fact that we want to be a part of
6 the solution not a part of the problem and anything we can
7 do to help that, I hope you will let us know.

8 Thank you.

9 CHAIRPERSON JANOSKY: Are there any questions from
10 panel members?

11 [No response.]

12 CHAIRPERSON JANOSKY: Well, Dr. Robert Jankelson?
13 Will you state your name, affiliation and the
14 nature of your financial interests, if any?

15 DR. JANKELSON: Good morning.

16 I am Dr. Robert Jankelson, associated with
17 Myotronics, Inc., and I do have a financial interest in that
18 company but I speak to you this morning as a private
19 practitioner and researcher in the area. Unfortunately the
20 term TMD carries with it philosophical connotations,
21 semantic obfuscations. It becomes inextricably tied to the
22 other subject in dentistry that is so contentious which is
23 occlusion, also, which is fraught with semantic
24 inconsistencies.

25 So, it's unfortunate that even in these advisory

1 panel discussions we always seem to have this issue of the
2 philosophy of treatment of the disease, et cetera.

3 What I would like to do, just very briefly, as the
4 panel members sit with your diverse backgrounds, degrees, et
5 cetera, let's not even think of TMD. Let's just think about
6 generic musculoskeletal dysfunction. The same thing that is
7 happening to the masticatory muscles histochemically in
8 dysfunction as happening to any other muscle in the body in
9 a similar dysfunction; likewise, the same incoordinations,
10 degenerative changes we see in the temporomandibular joint
11 are occurring in the knee, the hip.

12 I just had a total replacement of my shoulder six
13 weeks ago because of degenerative joint disease.

14 So, divorce the data, the objective data that
15 these measurement devices provide from TMD. Separate it
16 from the obfuscated semantics of occlusion and TMD that we,
17 as dentists, are all too aware of. And then ask yourself if
18 I am treating chronic dysfunctions, disease of the
19 musculoskeletal system? Is it of diagnostic import to have
20 objective data concerning dyskinesia, range of motion,
21 deviations? It is important to determine whether there are
22 sounds in joints that are indicative of incoordinations,
23 degeneration, et cetera? And it's that simple.

24 My feeling is that these are very important
25 diagnostic adjuncts, just as the American Dental

1 Association, Council on Scientific Affairs said, these
2 devices are not intended to make a diagnosis. They assist.
3 They are aids in the diagnostic process which is an
4 intuitive, a deductive process that all of us, as practicing
5 clinicians, employ every day.

6 So, I hope that provides one more perspective.
7 Within that context, since the devices are providing
8 objective data--no more than that--that assist the doctor in
9 having more information in making an appropriate diagnosis
10 and subsequent therapy, I feel that these devices
11 appropriately should be class I for the jaw tracking; and as
12 my brother made the distinguished separation between class I
13 for devices that only record and display joint sound versus
14 class II for those recording devices that make an
15 independent diagnosis.

16 Thank you and I will entertain any questions you
17 might have.

18 [No response.]

19 DR. JANKELSON: Thank you very much.

20 CHAIRPERSON JANOSKY: Thank you.

21 No questions from panel members.

22 [No response.]

23 CHAIRPERSON JANOSKY: Okay. Ms. Terri Cowley.

24 MS. COWLEY: Thank you, again, good morning.

25 I just wanted to make a few comments in response

1 to some of the statements that we heard yesterday afternoon.
2 In response to Dr. Jankelson's remark on the Vitek patients
3 it is impossible to know how many Vitek patients actually
4 were put on the instrumentation devices at one time or
5 another. And wouldn't it have been nice to have had
6 clinical trials with long-term follow-up on either the
7 instrumentation devices or the implants or both?

8 I do know one thing, I haven't heard one of the
9 mutilated patients tell me that they were put on
10 instrumentation devices to aid in the reconstruction of
11 their joints or teeth. They are barely able to find a
12 dentist who will even extract their broken teeth.

13 Yesterday, Dr. Cooper talked about his treatment
14 plans for patients, citing the function of the devices being
15 discussed as treatment aids. He also said that the
16 diagnosis was made before the use of the instrumentation
17 devices. However, he goes on to explain that these devices
18 are used to assess the progress the patient is making in the
19 road to the perfect alignment goal, kind of like a guidance
20 system. So, it seems it's just a little beyond the actual
21 stated purpose.

22 As Dr. Cooper went on down the treatment plan it
23 was clear he had everything to perfection. The mandibular
24 repositioning splint adjustments, metal partial dentures,
25 reconstruction of the teeth, crowns, bridges and

1 orthodonture. And in the event there is a joint problem
2 after that, the patient is referred to the oral surgeon.

3 The fact is there is a sort of triage to the
4 system; some get better, some may be unaffected; and some
5 get worse, just as with all of the other treatments we're
6 subjected to. We really don't know reasons why people were
7 lost to follow-up. Were they better, worse, died, went to
8 other doctors?

9 Was the patient selection criteria inappropriate
10 or do we do the same thing to every patient even though
11 there are multiple diseases, disorders, under this thing we
12 call TMJ?

13 In 1991, we invited an instrumentation device
14 devotee to speak to our monthly support group. After the
15 talk as I was speaking to the dentist a young woman
16 interrupted and told him that the previous month her dentist
17 told her she needed this testing. She went on to explain
18 that her insurance plan would not pay for these tests and
19 she could not afford the \$3,000 they cost.

20 He took her firmly by the arm, told her to go to
21 the bank the very next morning and borrow that money for
22 that would be the best investment she would ever make.

23 If these devices are strictly inert, so to speak,
24 and the diagnosis and treatment are operator-dependent, then
25 perhaps Dr. Cooper's techniques using the devices is perfect

1 and there is no one else with his "art" of dentistry. But
2 how do the patients know this?

3 And today we just heard Dr. Tilley uses a
4 different approach. And Dr. Jankelson said, forget the
5 philosophy of TMD but that's all we have to talk about
6 because we don't have the science of TMD to talk about.

7 So maybe we're back to uncertainty of treatment
8 results unless we get the machines and Dr. Cooper and now
9 Dr. Tilley and maybe these are the only two people who know
10 what TMD really is or J.

11 The treatment plan outlined above is costly, at
12 minimum, of \$3,000 for tests and evaluation. In New York
13 City \$2,000 for a splint, in Milwaukee, \$125 for each splint
14 adjustment.

15 The efficacy factor here should perhaps involve a
16 cost/benefit ratio analysis for the patient. The money
17 joint requires quite an outlay from the over 10 million
18 people seeking help. It still boggles my mind that in our
19 files we have a copy of a bill for a total joint replacement
20 procedure of \$101,000.

21 Perhaps those getting all this money could unite
22 and start a foundation to support scientific research on TMJ
23 diseases and disorders. An all too familiar story to us is
24 when the problem gets too big, bail out.

25 It goes like Connie in Ohio wrote on July 26th:

1 "It started six years ago. Anyhow I tried to get good care.
2 Everyone thought I needed a bridge. I was young and I
3 didn't know. So, a bridge is what I got. Then it seemed
4 like it was so big, bigger than my other teeth, so, the
5 dentist filed the teeth on each outer side, top and bottom,
6 cut my molars off and told me to, well, have a good day.

7 "After the fusion in my neck, I couldn't close my
8 mouth all the way. So, I was talked into splint therapy and
9 manipulation. Pain all the way. Then the dentist said,
10 I've run out of ideas and sent me somewhere else.

11 "The next dentist made two lower splints. I kept
12 telling him the splints felt very uncomfortable. In 10
13 weeks he yelled, saying he could no longer help me.

14 "Off to the jaw surgeon. Praying for help. He
15 told me it was neuro-muscular and neurological and couldn't
16 help me. Yet, in the report, he said, skeletal-facial
17 deformity and class III open bite.

18 "So, I returned to the nightmare here. The
19 massage therapist I've been seeing tried to line up my sinus
20 bones and pressed extremely hard above my right ear in my
21 skull. After that, no one would fill my teeth. The jaw,
22 right jaw locked open and seemed to go left. Then my skull
23 started to become numb over my ear."

24 She goes on but ends the letter by saying:

25 "Dreaming I could have my life back, simple as it was, I am

1 in so much pain and will go anywhere and do anything if I
2 thought I'd stand half a chance. I just hope someone can
3 still help me put me. Could it be you?"

4 If there are 10,000 doctors treating TMJ and we
5 have over 10 million people with this problem and if only
6 each of these doctors has 100 failures, could they all be
7 this woman? 100,000 people, a million? Is it too much to
8 ask that we, the patients, no longer be bound to a system
9 where no one professional takes responsibility for the
10 patient?

11 A system of unbelievable referrals with
12 unscientific, unproven treatments and hope sold to the
13 patients by each referring physician? In many cases,
14 patients end up worse and more and more destitute. Yet,
15 they grasp for hope with each referral. Is it too much to
16 ask that we get the protection we deserve under the
17 Hippocratic Oath: To do no harm and the laws of the United
18 States?

19 Thank you.

20 CHAIRPERSON JANOSKY: Any questions?

21 Yes?

22 DR. GONZALES: Referring to what you said
23 yesterday, as well as what you've just stated, what is the
24 message that you're trying to give us, besides enormous
25 frustration which sounds very appropriate. What are you

1 trying to teach us or tell us today and yesterday?

2 MS. COWLEY: That we're desperate. We're
3 desperate to have this disease, disorder, scientifically
4 researched so that we can finally understand what is going
5 on when somebody has an air-bag blow off in their face and
6 ends up in surgery. When it is a 14-year old girl who
7 suddenly begins with jaw pain and ends up with implants at
8 the age of 16. We need to understand what this is.

9 We have gone for 50 years with fixes that
10 obviously might work in people or work in--or don't work but
11 the patient has no adverse reaction to the treatments and on
12 and on. We're desperate to get the research on treatments
13 for patients.

14 We're desperate to have the media understand what
15 the patients of this country are going through. We're
16 desperate to have the FDA do their job, the NIH spend money
17 on this disease. We need to recruit the best scientists we
18 can from other areas into this area.

19 We desperately need our medical doctors to
20 understand what we are dealing with because pain in the
21 back, in the shoulders, in the legs that accompany this with
22 so many of the patients, you don't go to your dentist if you
23 have back pain.

24 You are not treated, chronic pain is not treated
25 by dentists, quote/unquote. The damage we--we have patients

1 on feeding tubes, we have patients on dialysis because
2 people forgot to tell them stop taking all of the Advil for
3 two years. Education, understanding, research and
4 protection.

5 I think we need everything.

6 DR. ALTMAN: Don Altman.

7 I agree that the research is not ideal and
8 definitely needs to be there. Today's panel meeting is
9 about classifying two tracking devices. A couple of the
10 other speakers have told us that they think it should be
11 class I, some class II. Where do you stand on these
12 tracking devices?

13 MS. COWLEY: I almost prefer not to take a
14 position because you have had access to the hundreds,
15 obviously, the hundreds of documents that the manufacturer
16 submitted and I don't. I mean I haven't read them and I'm
17 sure if I asked them for them, I would have gotten them.

18 You have to do the assessment. Technically
19 speaking if a device is inert and the worst problem we could
20 have is that it blows up in your face, okay, it's an inert
21 device without the capability of hurting you. But as I said
22 yesterday, this device goes to all the doctors, okay?

23 What happens when it is in their hands and perhaps
24 the art of dentistry is where we are getting the damage, not
25 in the actual device. And, of course, that is your job to

1 decide, not mine.

2 And, so, I tried to tell everyone yesterday this
3 is--it's time that we have collaborations, cooperation, so
4 that we don't have another Vitek situation, where everybody
5 did what they thought they were doing. They all knew
6 something was going wrong but nobody spoke out. We have to
7 have some type of integrated system here. Let's--if these
8 devices are terrific--somewhere, somehow can't we get a
9 clinical trial?

10 How can we constantly be forced to tell patients,
11 if you have that done, you may get better, you may not get
12 better, and do you know how bad off you can be? I mean that
13 is really, that is--we don't have options. So, you deal
14 with the device classification.

15 I have to deal with the next step which is what
16 happens when it goes into the hands of professionals? And
17 then we have to worry about, is this device something where
18 you should be sending MDR reports back to the FDA and then I
19 have to figure out and find out from the General Accounting
20 Office if, in fact, there are, is there a backlog of MDR
21 reports filed and on and on?

22 So, it's like we have become this mechanism for
23 pulling together information, it seems. I don't know. Did
24 I answer that? If I didn't, just pretend I did.

25 MR. LARSON: Yesterday, you heard Dr. Jankelson

1 say that with the use of the instruments that there is less
2 surgery performed. Do you have a reaction to that?

3 MS. COWLEY: How do we know?

4 MR. LARSON: You don't--

5 MS. COWLEY: Do we have studies?

6 MR. LARSON: No.

7 MS. COWLEY: Pretend that every person--

8 MR. LARSON: No. I recognize that we don't have
9 the studies to answer that question but you do have a very
10 significant data base of patients. Now--

11 MS. COWLEY: Yeah, without anyone knowing we're
12 here.

13 MR. LARSON: Okay. Your patients tend to be those
14 who were operated. So, maybe it's--

15 MS. COWLEY: A lot of them.

16 MR. LARSON: --not the population that would help
17 us answer that question. But you don't have a reaction to
18 that statement?

19 MS. COWLEY: You see, let's just say that--let's
20 pretend that he is right, okay? But I will then get a
21 letter--we get letters, we get splints in the mail, we get
22 videotapes, we get documents from doctors. Their treatment
23 is the only one that works. In 1986, we interviewed every
24 doctor in the Milwaukee area when we started this support
25 group to find out, you know, how are they treating patients?

1 Because we thought we were the only two people who this
2 happened to or no one knew what to do.

3 Everyone of them, with the exception of maybe two,
4 were adamant that their treatment was the only one that
5 worked. Adamant. So, you go from one door to the next and
6 if theirs is the only one that works and you are in severe
7 pain, how do you make a decision as a patient?

8 So, and even if Dr. Jankelson's devices worked
9 beautifully, there is always another treatment that could've
10 triggered all of these people into Vitek implants. So, we
11 have no standards of care.

12 MR. LARSON: Okay. But we have to deal with the
13 devices, themselves.

14 MS. COWLEY: Yes.

15 DR. MOSES: Allen Moses. I have a point of
16 clarification, as a matter of fact. I'll share it
17 anecdotally with you. That when I saw the transcript of the
18 1994 meeting of the FDA panel, I was really extremely upset
19 because I do believe in the safety of these instruments
20 because I use them. And, so, I wrote to the FDA under the
21 Freedom of Information Act and I asked for every single
22 adverse reaction report from probably 1970 when they started
23 keeping them on this instrumentation or when the
24 instrumentation started.

25 And I got, actually I did get results. I got

1 microfiche tapes, about 30,000, every adverse reaction
2 report ever and it became my responsibility to go through
3 them. I share your frustrations. So, when I was at the
4 November 1997 meeting here, I brought that exact point up.
5 And as a point of clarification Dr. Betz answered that
6 question and he said, that during the entire time that this
7 instrumentation has been available there haven't been an
8 adverse reaction report. There has never been one--

9 MS. COWLEY: Sure.

10 DR. MOSES: Okay. So, but, on the other hand, I
11 want to clarify that again. In that quarterly, every doctor
12 gets a bulletin from the FDA, the back page of that bulletin
13 is an adverse reaction report. And I would say that every
14 doctor has more than just an inclination, it's an obligation
15 to fill that out, if there is an adverse reaction report.

16 MS. COWLEY: Well, but they now have the Medwatch
17 System and in discussing tone joints with one of the
18 manufacturers who is now marketing his device, he was
19 telling me that it is incredible how the surgeons don't have
20 a clue that they are supposed to file first an MDR report
21 and then, obviously, a Medwatch report. You know, this is
22 something that most doctors aren't even aware of.

23 DR. MOSES: Oh, I emphasize with you on that issue
24 but, on the other hand, you know, I feel that by doing
25 objective measurement or by conservative treatment we avoid

1 a lot of surgeries.

2 MS. COWLEY: Well, you know, you're talking about
3 objective measurement and I totally agree with you. And
4 perhaps wouldn't it be great if we had this objective
5 measurement and we followed people from the ages of perhaps
6 10 and had them up to the age of 25 and at the end of that
7 period we found that we were able to find a factor that we
8 could identify that is predisposed, well, that we could
9 identify a person who is going to get a TMJ problem.
10 Perhaps it would be that, about in the course of that type of
11 research and before people are treated.

12 DR. MOSES: I don't know that this is the place
13 for that discussion but, again, I totally share your
14 frustration here because I was equally frustrated, frankly,
15 when I sat here and I saw doctor and listened to what Dr.
16 Dionne said, and when he said that the NIH, NIDR doesn't
17 know what TMD is. I thought, wait a minute, they don't have
18 any diagnostic criteria. And, so, they don't know who has
19 the disease and who doesn't.

20 And then he said that they want randomized
21 controlled studies and the randomized controlled studies,
22 first they have to know who has the disease and who doesn't.
23 And they haven't told us that because they have no
24 diagnostic criteria.

25 MS. COWLEY: We don't have the basic--I am sorry,

1 I'm interrupting, but we don't know what it is. And, so, we
2 keep going in this circular merry-go-round now for 30 years
3 at least.

4 DR. MOSES: And, so, I don't think we're in an
5 opposition here because I think that what we're seeing is
6 that there are doctors like Dr. Cooper who didn't charge his
7 patients for that research, and who, in essence, did that
8 research on his time because he is a scientist.

9 And there is a degree of research that dentists
10 are capable of doing with this safe instrumentation in their
11 offices wherein they can help feed information to the
12 National Institute of Health as to what quality of research
13 is needed or where to go with this, what are we finding?
14 But they're not listening and I share that with you, the
15 frustration is ours as well.

16 But that doesn't mean that the use of this
17 instrumentation on a research basis isn't part of the
18 answer.

19 MS. COWLEY: Right.

20 CHAIRPERSON JANOSKY: One final panel member
21 question?

22 DR. TALLEY: Two observations and comments.

23 First, our charge here as this panel is to
24 classify these two instruments, not to debate the pros and
25 cons and issues associated with the raw multi-factorial

1 issue of temporomandibular disorders. However, I share very
2 clearly your frustration as a practitioner who fully
3 believes in clinical practice that we should use the most
4 conservative approach in both diagnostics and therapeutics
5 and treatment modalities.

6 I stand on the issues that: Do no harm and stay
7 away from those irreversible procedures and not just simply
8 surgery. There are other irreversible procedures, too, that
9 we do as dentists every day.

10 However, with the issues of the studies and the
11 almost transparent or apparent indictment of dentistry here
12 as a profession, I must also comment on two other types of
13 issues that I have at least random familiarity with.

14 The first of those has to do with issues such as
15 my 57-year old sister who is confronted with terminal breast
16 cancer and has been given options but there are no studies,
17 whatsoever, that prove that any of the treatments available
18 to her have efficacy or have any safety whatsoever. In
19 fact, they basically told her that she can maybe survive or
20 maybe the treatment will kill her.

21 So, in dentistry, we're not the only people that
22 are confronted with these type of issues. This is, TMD is
23 not the only area of medicine in the global sense that has a
24 lack of well-controlled, randomized, clinical studies to
25 prove the efficacy and safety of various treatment

1 modalities.

2 And the same thing is true with regard to coronary
3 bypass surgery when you look at the data that is available,
4 we're not looking at those things that prevent us from being
5 able to proceed with those procedures.

6 So, my charge here is that it is a very
7 frustrating system. It's a very difficult issue that we're
8 confronted with in the global sense of dealing with TMD.
9 But my only comment now is that we really need to move on to
10 the business that was handed to this panel which is to deal
11 with the classification of these two instruments.

12 MS. COWLEY: Can I just comment?

13 DR. TALLEY: Certainly.

14 MS. COWLEY: I also, yes, perhaps condemnation of
15 a profession, yep, a little bit. Also, a condemnation of
16 the medical community that constantly ignores us, refuses
17 even to treat the medical aspects of what we're going
18 through.

19 So, I appreciate your comments.

20 CHAIRPERSON JANOSKY: Ms. Cowley, would you please
21 state again for us your affiliation and your financial
22 interests?

23 MS. COWLEY: Oh. The TMJ Association and we have
24 no money.

25 [Laughter.]

1 DR. HEFFEZ: May I comment?

2 CHAIRPERSON JANOSKY: Sure, Dr. Heffez.

3 Are you addressing the question to Ms. Cowley

4 DR. HEFFEZ: No. To whoever of you is capable of
5 answering it.

6 CHAIRPERSON JANOSKY: Okay.

7 DR. HEFFEZ: It's known that the jaw tracking
8 devices, the recording of them, would be difficult. Am I
9 coming in too loud? Okay. It's known that any of the
10 implanted electronic devices in the body can interfere with
11 the recording of jaw tracking devices. I just would like to
12 know if anyone is aware that there is any precaution that
13 needs to be taken reciprocally? In other words, are the jaw
14 tracking devices, can they interfere with any implanted
15 electronic devices such as a pacemaker?

16 That's the end of the question.

17 CHAIRPERSON JANOSKY: Dr. Jankelson, you are going
18 to respond?

19 DR. JANKELSON: Dr. Robert Jankelson, associated
20 with Myotronics, I have a financial interest in the company.

21 There is absolutely no possibility of any
22 interference with either jaw tracking or sonography with any
23 type of implanted device. The only device that has any
24 possibility of such an effect would be the device that is
25 not a subject of classification today and that is TENS

1 devices which can interfere with demand pacemakers.

2 And since that is not a subject for classification
3 today, I answer you in that the two devices that are the
4 subject of classification today, there's absolutely no
5 possibility of interference with any type of implanted
6 device.

7 Thank you.

8 Any questions?

9 CHAIRPERSON JANOSKY: Dr. Heffez, do you have a
10 follow-up question?

11 DR. HEFFEZ: No. I'm fine with it.

12 DR. JANKELSON: There is no input signal into the
13 body, it is only recording output signals.

14 Thank you.

15 DR. HEFFEZ: The question was really whether the
16 machinery that is used in recording it, not necessarily
17 implanted on the patient, but in proximity to the patient,
18 has any importance?

19 CHAIRPERSON JANOSKY: I see a head nod from Dr.
20 Jankelson, is that--

21 DR. JANKELSON: The level of risk is no greater
22 than if you were close to your personal computer

23 Does that answer the question

24 DR. HEFFEZ: Thank you.

25 CHAIRPERSON JANOSKY: I would like to remind the

1 panel members to, please, state your name, so that the
2 transcribers can attribute the statements to the appropriate
3 panel member.

4 That's the completion of the list of everyone who
5 had requested to speak before the open public. Are there
6 any other requests?

7 [No response.]

8 CHAIRPERSON JANOSKY: My understanding, Dr.
9 Runner, is that you have received some comments that you
10 would like to share with the panel.

11 DR. RUNNER: Yes, thank you.

12 We received two more comments from outside
13 practitioners. The first was from, I believe, it's Dr. Rex
14 Eatman. I couldn't quite hear his name on the telephone but
15 I believe it is Dr. Rex Eatman. It sounded like Reatman,
16 but I think it's Rex Eatman. He stated that he had used,
17 for 14 years, the EMG and the computerized jaw tracking
18 devices and felt that they were essential in the diagnosis
19 and therapy of patients. He feels that the long-term
20 clinical use by a surgeon has helped avoid surgical cases.

21 And then another comment was received by Dr.
22 Martha Rich from Portland, Oregon, who stated that, "I have
23 used jaw-tracking and sonographic devices since
24 approximately 1986 for research purposes at the Oregon
25 Health Sciences University and in my own private practice.

1 I devote about 50 percent of my time to the diagnosis and
2 treatment of temporomandibular joint and maxillofacial
3 disorders.

4 "These instruments are safe, effective, non-
5 invasive, and reliable. They always work. They are very
6 sensitive. In fact, the jaw-tracking devices can measure
7 jaw movements to one-tenth of a millimeter. They are an
8 invaluable aid in helping my patients.

9 "It would be impossible for me to help people as I
10 do without these devices. I know a number of colleagues
11 that also use these devices and find them very helpful.

12 "To my knowledge there has never been an adverse
13 reaction to these devices. Due to the non-invasive nature
14 of these instruments, I recommend they be classified as
15 class I devices.

16 "Thank you for considering my testimony."

17 CHAIRPERSON JANOSKY: Okay. At this time, we will
18 close the open public hearing and we will move to the open
19 committee discussion.

20 My understanding is that Dr. Gutman has some
21 comments for us.

22 DR. GUTMAN: I would like to frame the discussion
23 by using some information I bring from my usual role as
24 Director of the Division of Clinical Laboratory Devices.
25 Dental products for me are a stretch, diagnostic products

1 are not.

2 And I want to share some perspectives. The FDA
3 doesn't have an obligation to maintain consistency across
4 product lines but we at least like to understand where our
5 consistencies and our inconsistencies lie and at least try
6 to understand why particular decisions are made.

7 When we talk about the safety of a diagnostic
8 product we, in fact, look quite differently than when we
9 look at the safety of a therapeutic product, and the issues
10 of being non-invasive or non-intrusive or non-harmful are
11 interesting but, generally, not very important. And when we
12 talk about the safety of a diagnostic product what we really
13 usually refer to are the impacts of false positive and false
14 negative results.

15 So, as you think about the safety of this product
16 I would request that you think of it in a slightly broader
17 context than you may be used to in looking at implants or
18 other products; that you think about it, not only in terms
19 of how in Dr. Alpert's word, it's not a question only of
20 contact but of impact of the information being generated.
21 So, that needs to frame your intellectual thoughts.

22 When we, in DCLD, the Division of Clinical Lab
23 Devices, look at classification, we look at the claim
24 structure and the exact same device--Dr. Alpert did point
25 this out, and I think it is so important that I want to

1 point it out again, maybe even twice--when we look at the
2 exact same device with different claims, may have totally
3 different classifications.

4 You may take a simple chemical analyte and if that
5 analyte is well understood and clearly used adjunctively as
6 part of a very complex pattern of laboratory testing,
7 integrated into a history of physical exam, radiographic
8 exams, other pieces of information, so that that piece of
9 information doesn't tip you into a treatment decision, we're
10 generally comfortable calling that a class I exempt device,
11 because it is truly an adjunctive piece of information.

12 The exact same test, if it was suddenly used as a
13 primary diagnostic that might impact treatment, that might
14 cause you to intervene, order a whole bunch of extra tests,
15 do an invasive radiographic procedure, endoscopy that might
16 cause you to do something more aggressive, surgery,
17 something more aggressive, that exact same device could be
18 class I reserved if it has historically been class I, which
19 means it would be reviewed not exempt or, more generally,
20 now days, would be class II, the exact same device.

21 And if that same device was suddenly used for some
22 very brand-new claim, it's diagnosing brain cancer or
23 diagnosing a new retro-virus, the same device might, in
24 fact, be a class III and be subject to a PMA.

25 So, we're very claims-driven and I will give you

1 an example of our most recent classification which has some
2 parallels--it's certainly an imperfect parallels--but some
3 parallels to the discussions of yesterday and today, and
4 that's what we've done with immunohistochemical stains.

5 For those of you who don't know, an
6 immunohistochemical stain is a stain for a--when you have
7 diagnosed a tumor and that stain will help you decide what
8 the mother cell for the tumor is.

9 When you have an anaplastic tumor the stain will
10 help you decide if it's a carcinoma or a sarcoma or a
11 lymphoma or whether it's from prostate or breast or lung by
12 giving you information about the antigens that trace the
13 history of that cell.

14 And our approach in classification which was a
15 labor of love but a long process, a four or five year
16 process, with a lot of interaction with both professionals
17 and manufacturers was that we--there are certain parallels--
18 that cancer is not diagnosed using special stains, it's
19 diagnosed by pathologists using an agent H&E stain on often
20 a frozen section, sometimes a fixed section, and make a
21 diagnosis of cancer.

22 Sometimes the story is over but sometimes that
23 diagnosis doesn't provide enough information so you really
24 know what the tumor is and in that case, you probably will
25 order five or 10 immunohistochemical stains and see if it is

1 negative for lymphoma and positive for carcinoma and
2 negative for sarcoma and you make a diagnosis. But it's
3 adjunctive information that's fed into the sex and age and
4 nature of location of the lesion. You are using it
5 adjunctively. We decided that was class I exempt.

6 . That same stain if someone came through and made a
7 claim that that stain, by itself, diagnosed lymphoma or by
8 itself determined you should start estrogen therapy or by
9 itself suggested that the patient had a six-month course to
10 live, that same stain with more distinctive claims would be
11 a class II. And, in fact, if that same stain were used to
12 replace frozen sections for cancer of the breast and you
13 started doing mastectomies using that information, that same
14 stain would be a class III. So, we're claims-driven.

15 So, my request, our request would be that as you
16 look at this classification, you frame your discussion in
17 terms of identifying claims. And actually I think that Dr.
18 Jankelson has put it exactly right, as to what information
19 do you need to understand whether an instrument does what it
20 claims to do? So, you have to know what it claims to do.

21 And you have a number of choices. I think you
22 were trained yesterday, but I want to walk through the
23 choices with you, again, so, you at least understand them.
24 The choices are, at a minimum, they are devices, but at a
25 minimum you can suggest that they have no review and if you

1 suggest they have no review, that doesn't mean there is no
2 regulation.

3 There is, in fact, regulation and that regulation
4 primarily falls into two categories if these are still
5 required to meet the quality system regulations of good
6 manufacturing practices.

7 So, they still have to be made according to how
8 they are going to be labeled and they are subject to a post-
9 market requirement. The MDR may be imperfect but it still
10 is the law and if there are things that go wrong they will
11 be required.

12 Most products that are subject to no review, to
13 exemption, are class I. It is theoretically possible to
14 have a class II product that is not reviewed and the common
15 theme that strikes me as fueling and it's worth probably
16 some discussion as you are entertaining what to do with this
17 is if you make a choice to make it exempt, whether you are
18 satisfied with the usual quality system regulations or
19 whether you would like a little bit more for your money in
20 terms of GMP, there is a system called Design Controls. The
21 design controls fit all class II products. They can be
22 appended to class I products.

23 And they are not fundamentally different from the
24 quality system regulations but they add a certain
25 specificity and focus to the quality system regulations in

1 that they put a requirement on the manufacturer to have both
2 input and output and constantly link the two. And you might
3 want to think about that as something you may think is
4 unnecessary for this product line or may be valuable for
5 this product line as you are moving forward.

6 DR. MOSES: Can you speak more to that, the design
7 controls in terms of input and output?

8 DR. GUTMAN: Well, the quality system regulations
9 requires an accountability. It's essentially total quality
10 management or continuous quality improvement incorporated
11 into the manufacturing process. And the manufacturers are
12 required to do that for a device come hell or high water.
13 That is an obligation.

14 The Design Control puts a little bit of focus in
15 terms of you establish your objectives up-front. Your
16 objective might be to produce waves at a certain frequency
17 or to be able to visualize. Those waves have to be able to
18 visualize certain structures at a certain reliability
19 precision, penetrate.

20 I don't know what I'm talking about here, as you
21 can see, but the bottom line is you set your objectives and
22 then the company has an obligation using either analytical
23 data, clinical data or the manufacturing process, itself, to
24 validate that it knows what its doing and it can ensure that
25 what it starts with produces a product that is meeting its

1 objectives, its goals and its labeling. And it simply adds
2 specificity. I don't know that there is a fundamental
3 difference. Dr. Alpert might want to jump in. It adds a
4 little bit of specificity.

5 DR. MOSES: Does the device have design controls
6 and be class I?

7 DR. GUTMAN: Absolutely.

8 DR. ALPERT: Now, what design controls addresses
9 is a company defining up-front what the expectation is for
10 their product. So, if they design a product to be sensitive
11 at a certain level to be able to detect sound at a certain
12 level or to be able to measure movement at a certain level.
13 That's their objective for their product. And then they
14 design their product and they test it to see if it meets
15 those objectives. That's the kind of issue.

16 So, they will spell out in a file, in a
17 manufacturing file, what their objectives are, the kinds of
18 testing that they are going to do to demonstrate that they
19 meet those objectives. And then they put their product,
20 when they actually design the product, through the process
21 that they have laid out and demonstrate in their own files
22 that they have met their design objectives.

23 That, in fact, the product produces or measures
24 what it is intended to produce or measure in a reliable way
25 and that they, therefore, have a process, a manufacturing

1 process that will reliably and continually produce that same
2 product.

3 For example, devices, as I'm sure all of you know,
4 are constantly being tinkered with. Engineers don't like to
5 leave things alone and, so, they are always changing
6 something about the device or its manufacture. When you
7 have a design controls process, every time you make those
8 kinds of changes you test against what you say your output
9 parameters are going to be for your product.

10 So, you can make changes and then you test and
11 document that, in fact, you continue to meet the criteria
12 that you, the manufacturer, have put in place for that
13 product. That is, in the design controls files, the design
14 controls provision in the quality systems regulation which
15 went into effect last year, is an approach where the agency
16 is requiring that manufacturers of class II and class III
17 products and identified class I products have such a file in
18 place that is inspectable. So, they have a responsibility
19 to have that documentation and we have the authority to go
20 in and look at that documentation as part of our inspection,
21 our ongoing inspection process with manufacturers.

22 DR. MOSES: So, is my understanding right that if
23 these devices are on the market today that then they would
24 not need pre-market approval but post-market reporting of
25 these device changes which would be actually their own

1 initiative?

2 DR. ALPERT: Yes, and it is a bit of this and a
3 bit of that. Products that were in the market place have
4 been in the market place, that have not changed, continue to
5 be manufactured.

6 But if a company makes changes--and as I said,
7 most companies make changes and not all changes rise to the
8 threshold of needing a new clearance from the FDA--this file
9 applies to all kinds of changes, not just the ones that
10 would trigger a new pre-market submission. They are a
11 different threshold.

12 The quality systems approach has to do with day-
13 to-day manufacturing. And then there are those kinds of
14 changes which impact safety and effectiveness which also
15 trigger a pre-market look for class II and class III
16 products, not all class Is. And there are also--MDR applies
17 essentially across-the-board.

18 Did that help?

19 DR. MOSES: Thank you.

20 DR. GUTMAN: Well, one option is to have no
21 review. A second option is to have a review that involves
22 some form of special control. That would be the class II
23 product. And you have a variety of options you could
24 recommend in that special control and those options would,
25 frankly, again be predicated on making sure the instrument

1 does what it claims to do.

2 Those options could be analytical requirements to
3 make sure it does what it is supposed to do. They could be
4 clinical requirements to make sure it does what it is
5 supposed to do. Or they could be labeling requirements to
6 make sure that it does what it is supposed to do or it could
7 be any combination of the above.

8 And the notion here is that good manufacturing
9 practices alone and even with design controls and/or the
10 post-market surveillance do not quite fit the bill in terms
11 of making sure that the product does what it wants to do and
12 you would like a little bit of extra assurance and the extra
13 assurance is to have FDA review these before they enter the
14 market place.

15 And last, but certainly not least, is that if you
16 think that the product is fundamentally uncertain in terms
17 of its safety and effectiveness, if there are new issues of
18 safety and effectiveness. If there are issues that require
19 more intense review, that require not only the certainty of
20 a robust scientific review, but require more vigilant up-
21 front GMP, good manufacturing practice, review perhaps a
22 more intense bio-research monitoring review, and/or more
23 vigilance in terms of changes so that we are requiring
24 annual reports, then the third choice is to make these class
25 III and ask for a pre-market approval application.

1 The science between a complex class II and class
2 III products are blurring because we tend to be driven by
3 the scientific issues driven by the claim. But, in all
4 honesty, there are administrative differences between these
5 two processes that we have not entirely tamed and that the
6 PMA, in general, is viewed by manufacturers as more of a
7 burden. But in some cases it may be a necessary or
8 appropriate burden.

9 The last point I would like to simply address is
10 the fact that there have been some changes in our approach
11 towards the issue of labeling and promotion as a result of
12 FDMA, the modernization act last year, which I think gives
13 manufacturer's not a free rein, but perhaps a little bit
14 more freedom in terms the way they can handle a device. And
15 that is that for a 510(k), the FDA has fairly firm
16 instructions to look at claims in the context of the four
17 corners of the label.

18 So, we look at what the company claims. We don't
19 necessarily look at all of the implications and all of the
20 extra possible uses. Now, if we are very hung up about
21 that, we do have the right to go to speak to Dr. Alpert.
22 And she does have the authority in a package insert or in
23 the label, if there is real public health concerns about a
24 possible unusual use, off-label use or marginal use of
25 products, she does have the authority to put in restrictions

1 in that label. But we wouldn't do that except in very
2 special cases. We would not do that as a matter of rule.

3 And if you have hang-ups about it, you can
4 certainly recommend as part of a special control, we take
5 that into account.

6 Or, frankly, as part of the classification
7 process it is okay sometimes to put suggestions on labeling
8 restrictions or suggestions on limits to the way you might
9 classify a class I exempt product.

10 Again, we have my own favorite choice which is a
11 beast called the Analyte-Specific Reagent and we allow those
12 to go out for pre-market review without pre-market review,
13 but we do require some special labeling to make sure that
14 people understand that they have not undergone an ordinary
15 review.

16 So, you have a wide variety of choices. We are--
17 certainly from my perspective, I am learning and I would be
18 fascinated to understand how you see the claims of these
19 products, what kinds of controls that you think are
20 necessary to support these claims.

21 And I think that will lead to perhaps not ease but
22 certainly clarity in moving forward in the classification
23 process.

24 CHAIRPERSON JANOSKY: Dr. Runner, do you have some
25 additional comments for us?

1 DR. RUNNER: Do you want me at this time to go
2 through the comments that were received on those two
3 specific devices in terms of their classification?

4 CHAIRPERSON JANOSKY: That would be a reasonable
5 way to start.

6 DR. RUNNER: Okay. And then you can proceed with
7 your discussion. Just a second.

8 DR. BERTRAND: May I ask a question?

9 CHAIRPERSON JANOSKY: Sure.

10 DR. BERTRAND: Peter Bertrand. I have a question
11 for Dr. Gutman. When we're looking at classifying,
12 according to safety and efficacy, diagnostic data, something
13 that records, part of our intellectual decision process is
14 based in our perception of how that data might be used in a
15 clinical situation by the whole scope of different types of
16 practitioners who might be using that.

17 DR. GUTMAN: Absolutely.

18 DR. RUNNER: We did receive comments on several of
19 the devices classified, but I'm going to restrict my
20 comments to the two categories of devices that are under
21 consideration for classification.

22 One comment came from a party that believed that
23 the sonogram should be class I. The comment was that the
24 dental ESG or sonogram is not applied to life-threatening
25 pathology and, most importantly, unlike ESG devices marketed

1 by one company, the ESG from this company only records and
2 displays joint sounds, frequency, duration, and amplitude.
3 It does not interpret the recorded data, making no claims
4 that the device produces diagnosis or interpretation. Our
5 device and claims for its utilization are limited to its
6 function as a recording and display device.

7 He further states that a device which is intended
8 and claimed to analyze, record, and interpret recorded joint
9 sound data is a distinct device from a sonography device
10 that records and displays data only. The two should not be
11 confused. A separate and distinct classification should be
12 recommended for any device that claims to make a diagnostic
13 analysis or otherwise interpret the data for the using
14 clinician.

15 The second comment was on the kinesiograph. The
16 FDA table recognized the pantograph and goniometer as
17 comprising existing classification regulations relevant to
18 this generic type. We agree with the FDA table language as
19 follows: identify freeway space, identify mandibular rest
20 position, record relationship of the mandible to the base of
21 the skull. However, we would call your attention to the FDA
22 table's language which states that the kinesiograph provides
23 an interpretation of jaw movements. The word
24 "interpretation" suggests that the kinesiograph provides an
25 analysis or clinical evaluation when, in fact, the

1 interpretation and analysis is made by the clinician. The
2 kinesiograph does not analyze or interpret the data. The
3 clinician does that. The resulting data is intended, like
4 the EMG data and the ESG data, to be used by the clinician
5 together with all other information available, based on the
6 clinician's training, experience, and skill, to arrive at a
7 diagnosis and treatment plan and to monitor progress of that
8 treatment plan. In arriving at an appropriate
9 classification, the Panel should recognize that the
10 kinesiograph is a data-recording device only, a measurement
11 device that provides a level of objectivity,
12 reproducibility, and accuracy not heretofore available. A
13 class I classification appears appropriate.

14 Those are the only two comments that we had on
15 those two devices.

16 CHAIRPERSON JANOSKY: Thank you.

17 At this time, any discussion?

18 DR. RUNNER: I did want to make one other comment.
19 In the 510(k) submissions that we do have, we do have, as
20 Dr. Gutman said, draft labeling, and we don't have access to
21 all of the labeling and promotional material that is
22 presented by the company. However, we depend on inspections
23 for that information.

24 The second point is that although we have focused
25 on the claims we have in 510(k)s now, we do have information

1 on other claims, particularly about the sonograph in terms
2 of interpreting data, which is why I brought that up and why
3 that's on the table.

4 DR. TALLEY: Bob Talley, Panel consultant. Dr.
5 Runner, please hold it for a moment because my question may
6 be best addressed by you.

7 You just stated that this Panel does not have
8 before it the actual claims that manufacturers make. Is
9 that correct or incorrect?

10 DR. RUNNER: On the table that you have, on the
11 grid, the claims that are in the column stated TMD specific
12 intended uses in legally marketed devices, that is a summary
13 of the claims that have been seen in the 510(k)s. So if you look
14 under sonograph, it is both--we have seen claims both to
15 classify and interpret specific joint sounds, and to measure
16 and record sounds emitted from the TM joint as a means of
17 assessing the TMJ status. So all of those claims are ones
18 that we have seen.

19 DR. TALLEY: And if I understand correctly, the
20 two manufacturers represented here in the past day and a
21 half manufacture sonographic equipment, one of which
22 disclaims that they make any claims of interpretation and
23 one who had--there has been at least innuendo that the other
24 does make those claims. Is that correct?

25 DR. RUNNER: Yes.

1 DR. TALLEY: My next question--and, again, I may
2 be ahead of the Panel on this--is: In our classification,
3 can we place specific requirements on one without the other?
4 Or do they have to be classified identically?

5 DR. RUNNER: Yes, you can place one claim as one
6 class and another claim as another class.

7 DR. TALLEY: Thank you.

8 DR. ALPERT: And if I may, one more interruption,
9 to point out--because it is important in understanding the
10 process and how important it is, in fact, to consider the
11 claims currently made and claims reasonably recognized as
12 being made for the devices, even if they're not in current
13 labels. And the reason I point that out is one of the
14 points made by both manufacturers and by several of the
15 Panel members is that although there are some claims that
16 appear on labels, there are other claims being made either
17 in advertising and promotion materials or at meetings for
18 these same devices.

19 One of the things that we ought to consider, that
20 you ought to consider, is the claims on the current devices,
21 the claims being made by individuals about those devices,
22 and identify those and classify them, the reason being if,
23 for example, we are to classify one of these products into
24 class I exempt for a very general claim of recording, if we
25 don't address the devices and classify those that not only

1 record but set criteria, then by statute, by law, a
2 manufacturer coming in with the same product wanting to make
3 a specific claim about interpretation would fall outside,
4 likely fall outside the class I exempt and fall
5 automatically, by statute, into PMA.

6 . So if, in fact, we--you--recognize that there are
7 claims being made for these devices that are reasonable
8 claims for them, you might want to consider where they
9 belong and classify them, even though today no manufacturer
10 has made that specific claim on their label. It would allow
11 them a pathway should they choose to make that claim.
12 Otherwise, they automatically almost fall into class III.
13 They would have to come in and make an argument as to why
14 that specific thing is a general claim. That is tricky in
15 some cases.

16 So if you are aware already of these kinds of more
17 specific claims, it's appropriate to consider them and make
18 recommendations about their classification.

19 DR. HEFFEZ: May I ask a question?

20 MS. SCOTT: Yes. Go ahead, Dr. Heffez.

21 DR. HEFFEZ: Today, are we to only consider these
22 instruments as diagnostic instruments as opposed to
23 treatment instruments?

24 DR. ALPERT: If I understand your question
25 correctly, again, it's a matter of what are the claims. If

1 the claim is for providing basic information, then you might
2 look to say: Is that information as an adjunct to making an
3 assessment of a patient? Or in some cases--and Dr. Gutman
4 can speak to this as well--some devices of the same sort
5 make a claim for monitoring patients during treatment, but,
6 again, aren't making a treatment claim. They are not
7 providing the treatment. They are used to either provide
8 information for diagnosis or monitoring patients during
9 treatment with other interventions--surgical,
10 pharmaceutical, other devices.

11 Did that answer your question, sir?

12 DR. HEFFEZ: Well, is the safety of an instrument
13 changed whether an individual uses it to obtain diagnostic
14 information or whether that person chooses to utilize that
15 diagnostic information to make treatment decisions? Is
16 there a difference?

17 DR. ALPERT: We are not--the FDA doesn't regulate
18 the practitioner and what they do with the information. We
19 focus on what the manufacturer of the instrument says in
20 their labeling and in their marketing and promotion to the
21 practitioner as to what the uses of this information are.

22 So a device that claims to provide a certain type
23 of assessment, if a practitioner takes that assessment and
24 makes a diagnosis using that assessment, that's not the
25 responsibility of the manufacturer. If, on the other hand,

1 the manufacturer says you may use this device to monitor, to
2 set an outcome and monitor against that outcome, and the
3 manufacturer is saying it, then, in fact, we would regulate
4 whether or not the device actually performs that way.

5 If a device were to claim that it impacts the
6 disease, again, if the manufacturer claims that the device
7 impacts the disease, we would regulate that claim. But we
8 don't regular what--as Dr. Gutman pointed out, we don't
9 regulate what the practitioner does with the information as
10 much as what the manufacturer says, in this case, the
11 information will provide to the practitioner.

12 DR. GUTMAN: But can I just add a word? Even in
13 this case where you might have information that might change
14 or dictate changes or fine-tune your therapy, the strength
15 of the signal, the strength of the information is really
16 important. If it's an adjunctive piece and it's being used
17 with other information so you're moderating your therapy but
18 you're not using this as the stand-alone information to
19 moderate your therapy, that's different than if, for
20 example--again, I hate to keep going back to my shop, but
21 it's irresistible. If you have a CEA and you run it and
22 it's high and you suddenly do an exploratory lap looking for
23 recurrent cancer based on that chemical alone, that's a
24 stand-alone, and we would be horrified if it were exempted.

25 DR. ALPERT: If the company who manufactures it

1 makes that claim. Again, if a practitioner takes the
2 information and decides that they're going to manage a
3 patient in a certain way, that is not where we are. We are
4 where the manufacturer says you may use this CEA, and if the
5 CEA hits this threshold, that patient has recurrent cancer
6 and you need to do something. That's where we get involved.

7 DR. ALTMAN: Don Altman. I have a problem with
8 that, and I'm not sure that what you said is not what I
9 heard you just say.

10 As pure tracking devices--and they say that's just
11 what they do--I understand that and I don't have a problem
12 with that. Where I have a problem is that while the
13 manufacturer will tell the clinician how to use that device,
14 if it doesn't tell them what that's for or how to interpret
15 that, who does? You know, as somebody looking out for the
16 patient here, if nobody is training this clinician on why
17 they're doing that in the first place, then we could have
18 harm. And I heard Dr. Gutman say that we needed to look at
19 the potential of what that information could be used for and
20 could cause harm. And that's not what I heard you say.

21 DR. ALPERT: They are different aspects of the
22 same issue. What Dr. Gutman was talking to is the safety
23 and effectiveness established for the product. When you
24 make an assessment that something is safe and effective,
25 effective has to do with it has impact, significant impact

1 on a significant portion of the affected population. In the
2 case of diagnostic information, it means the information has
3 meaning to the practitioner.

4 It may be a within-patient assessment. It may be
5 measuring the patient at baseline and monitoring them over
6 time. It may be being able to determine that there are
7 abnormalities in normal function that can be detected by
8 this piece of equipment, but it doesn't tell you what the
9 diagnosis is for the patient. It tells you that there's
10 something not normal about the performance of a joint, about
11 the state of a tissue.

12 DR. ALTMAN: Can I interrupt right there?

13 DR. ALPERT: Sure.

14 DR. ALTMAN: You said it tells you that something
15 is not normal. So isn't that somewhat of a diagnosis?

16 DR. ALPERT: It is the ability--

17 DR. ALTMAN: By itself?

18 DR. ALPERT: Yes, it's the ability to figure out
19 whether or not the information is reflecting conditions of
20 patients, and conditions can be--you know, you can say--for
21 lab values, for example, lab values can be all over the
22 place, and you can say, well, if you look at 1,000 patients,
23 here's what our norm is for our laboratory for this test.

24 Now, a patient comes in and they're outside it.
25 It doesn't tell you that they have a diagnosis. It just

1 tells you they're outside the norm.

2 DR. ALTMAN: Do these products--and excuse my
3 ignorance, but do these products tell the clinician not only
4 how to use it but information you may get what is outside
5 the norm and what isn't? Or is that up for the clinician to
6 somehow get a CE for something like that?

7 DR. RUNNER: I believe that none of the devices--
8 the sonographic devices that I said interpreted, had
9 interpretive information in their labeling did give some
10 information as to norms and what would be normal and what
11 would be outside of normal and what certain sounds would
12 mean. I'm not aware that any of the other devices give
13 information specifically that say if you get this, it means
14 this.

15 DR. ALTMAN: So it truly is up to the clinician to
16 know what they're doing with that information, which is
17 something that we have nothing to do with. Is that--

18 DR. ALTMAN: The issue of not having something to
19 do with it has, again, to do with this issue of the claim
20 being made and a determination that effectiveness has been
21 established by the literature in this case, because these
22 are pre-amendments devices; that there is sufficient
23 evidence, valid scientific evidence to say that these are
24 effective, an effective means that they provide in the case
25 of diagnostics, information that is meaningful to

1 practitioners. It doesn't mean that we know--I think what
2 we're struggling here with is the fact that we are looking
3 at this information in an environment where all of the
4 science is not on the table yet regarding differentiating
5 patients with different degrees of pain, with different
6 degrees of abnormality in jaw movement, different degrees of
7 sound being made by a joint. And I think we all share as
8 scientists the idea that, well, there seems to be a
9 disconnect between what we are asking you to do and the fact
10 that there isn't a firm categorization for the patients.

11 For our work, that's not required. We are at an
12 earlier stage in this disease process, although I understand
13 the frustration of the patients that it's been 50 years and
14 we still don't know a lot. But the fact of the matter is
15 that we are early here. These devices are claiming and have
16 been on the market providing information about patients who
17 present to licensed practitioners who are going to have to
18 deal with the problems of these patients.

19 The fact that we have not reached the maturity in
20 the global environment, in the clinical environment, to be
21 able to definitively differentiate among patients isn't
22 required for putting the products on the market. It would
23 be better. It would be more helpful, make our jobs all
24 easier, but isn't a basic requirement.

25 The requirement for safety and effectiveness is:

1 Does the device provide something that is both consistent,
2 reliable, and meaningful to practitioners? We are at the
3 first step. We would all like to be at the last step, but
4 we are at the first step. We are earlier in the process.
5 And I think that there's been a lot said today that
6 indicates that this is an area ripe for research to
7 determine how--once people recognize that there are, in
8 fact, these questions, to now encourage research in the
9 environment to answer the questions that have been raised
10 here.

11 Now we measure. We record sound. Now, how do we
12 tell new practitioners what this means? Right now it's
13 being taught from practitioner to practitioner, sort of like
14 surgical instruments, you know. Your senior surgeon or your
15 chief resident taught you how to do the operation with the
16 tools, and you have to teach the next guy coming through,
17 the student and the fellow coming through.

18 Unfortunately, that is where we are with many
19 technologies. It is not in dentistry alone. It is in many
20 of our areas where the instrumentation is available to do
21 certain things, but we don't know exactly how to convey the
22 perfect use, the best practices use. And that's something
23 that the clinical community has to take on. The question
24 that we have to answer today is: Is there valuable
25 information being provided by these devices that can be used

1 by practitioners who understand how to use them? And what
2 are the risks in the claims to patients? What are the risks
3 to patients from using them in certain ways? If it is
4 simply to provide information and then it is really the
5 practitioner's responsibility to interpret, or if the
6 manufacturer is saying here's a threshold for you, does that
7 pose more risk to the patient? And that has to do with how
8 much information is already available on those claims and
9 whether or not you feel that the claims are so well
10 established that, well, it's clear that we don't need to be
11 there. We, the FDA, don't need to be there anymore. Or
12 should there have been testing or should their device have
13 to reach a certain performance in order to make that claim?
14 That is the kind of thing we do get involved in.

15 DR. ALTMAN: Okay. Well, then, I would like to
16 say that--it's not towards you. I think I understand where
17 you're coming from. I guess, you know, I think the devices
18 are valuable for those that know how to use them. I think
19 whether or not this Panel classified them I or II,
20 practitioners will still continue to use them in the manner
21 that they're using them.

22 I guess my concern is that if we put, say,
23 labeling restrictions or whatever, does that really affect
24 the use by the clinician to do any different than what
25 they're doing now?

1 DR. ALPERT: We believe that the labeling and the
2 information we place on labeling has several effects. One
3 is it does limit the manufacturer in what they can claim,
4 whether that is in writing or when they go out to market and
5 promote their product. That is one, and I believe Mr.
6 Jankelson spoke to that issue.

7 Two, we do monitor what they say. We are not out
8 there--we don't see every piece of advertising. We don't
9 see every label because in 510(k), in class I and class II
10 products, most of the changes that take place to labeling
11 take place without us. Unless they make a new written
12 claim, they're not necessarily required to come in to us.
13 So there's a lot of words being put in labeling that we
14 don't see unless someone brings it to our attention, either
15 a practitioner who sends it in to us and says, Is this
16 really what this device is approved for? And we'll answer
17 that or investigate. Or a competitor says, oh, these guys
18 are making a claim that is well beyond what we know is their
19 cleared labeling, FDA, your job. And we do go out and
20 investigate.

21 The second thing that labeling provides to the
22 practitioner is it tells the practitioner what has been
23 validated and evaluated by either a classification, if it's
24 a class I exempt, or through a 510(k) or PMA if there's been
25 a premarket process. And it says to you this has been

1 established; there's data to support this claim. But if the
2 claims aren't on the label, there isn't data to support
3 those claims. There may be publications. There may be
4 experience and knowledge in the community. But it hasn't
5 come through this independent vetting process. That's what
6 it says. And it says, hopefully, for those kinds of claims
7 you need to look further.

8 DR. BURTON: A couple of comments after sitting
9 here for a day and a half. One question: Can we classify
10 them as class I with labeling restrictions? Is that part of
11 the class I process?

12 DR. ALPERT: Yes and no. In general, the labeling
13 that is automatic--there are specific things that are
14 routine labeling that come with any classified product. It
15 has to do with accuracy, with not being outside of the
16 established claim, so that you're classifying a claim, they
17 can't make claims other than the one that's been identified
18 and classified.

19 The second kind of restriction, they have an
20 obligation to put in contraindications, warnings, and
21 precautions appropriate to the product. And they can't
22 misbrand, they can't label the device in ways that are not
23 accurate. So the labeling has to really reflect what the
24 device is and what it does. And that's assured by our
25 inspection process. As I said, there is a routine

1 inspection process that takes place where manufacturers have
2 FDA inspectors come in and look at not just how they
3 manufacture but other parts of their manufacturing, their
4 claims, what they're saying about their product.

5 Labeling restrictions, Dr. Gutman talked to the
6 fact that if we want to restrict with a labeling specific
7 statement a class I device, we can do that. It makes them
8 restricted devices, and that's a notice and comment
9 rulemaking process, and that can be part of this
10 classification. So you can do that. It's unusual, however,
11 to restrict on labeling for standard devices. We only have
12 two categories of devices currently that are class I and
13 restricted in terms of what they can say. The analyte-
14 specific reagents that Dr. Gutman spoke to have a labeling
15 restriction that the laboratories have to say that these
16 tests were done with these kinds of reagents and not with an
17 approved test. And hearing aids, which are class I exempt
18 and restricted, restricted to who can fit them. So it's
19 unusual.

20 The kinds of labeling restrictions that we put on
21 in class II have to do with very specific things that we
22 want everything in a class to say, even product in the class
23 must say, literally must say this, and if they don't say it,
24 they're misbranded.

25 The general labeling, however, assures--general

1 labeling of medical devices assures that the labeling is
2 accurate, that it is not outside of the claim, and that it
3 is factual. That comes in the package. That comes with
4 being an cleared or approved device, and we regulate
5 labeling to assure that it meets all of those criteria. We
6 have the authority to regulate the labeling of even class I
7 exempt devices. They are still devices, and we still
8 regulate them.

9 DR. RUNNER: But if it was class I, it would be
10 exempt.

11 DR. ALPERT: Exempt only means exempt from
12 premarket notification. It doesn't mean they're exempt from
13 oversight and misbranding. All of that applies to
14 everything that we regulate, even if we don't do premarket
15 evaluation before something enters the marketplace. As was
16 pointed out, it doesn't mean they're not regulated. It's
17 only one piece of the way we regulate. We're only one step
18 in a much larger process.

19 Did that answer your question?

20 DR. BURTON: Yes. Thank you.

21 MR. LARSON: Floyd Larson. Going back for a
22 moment to the intended uses listed in the grid, I recognize
23 that those are an amalgamation of intended uses from 510(k)s
24 that you've seen. Is it appropriate for the Panel to ask
25 manufacturers to give us more detail for this process?

1 DR. RUNNER: If that's what you wish, certainly.

2 MR. LARSON: I'm just wondering if that would be
3 helpful to the process to see what is actually out there in
4 the marketplace.

5 DR. RUNNER: Certainly you can ask that question.

6 CHAIRPERSON JANOSKY: Would you like to address
7 the question?

8 MR. LARSON: I guess we have--do we have only one
9 manufacturer here today? Is there more detail that we can
10 have besides what's in the 510(k)?

11 MR. ROLAND JANKELSON: I'm Roland Jankelson with
12 Myotronics. A point of clarification on the labeling. The
13 labeling that we--the claims that we can make legally are
14 presently set by the existing 510(k)s. That's the--

15 CHAIRPERSON JANOSKY: Excuse me, Mr. Jankelson.
16 Could you please go a little closer to the microphone?

17 MR. ROLAND JANKELSON: Is that better?

18 CHAIRPERSON JANOSKY: Yes.

19 MR. ROLAND JANKELSON: The 510(k)s regulate the
20 claims that we as a manufacturer can legally make. I read
21 from the 510(k) this morning. That describes in its
22 entirety the claims that we can make with respect to our
23 sonography device.

24 The grid language for the kinesiograph, in fact,
25 describes what the 510(k) prescribes for us as the claims

1 that we can make for that device, that it is a device that
2 records certain information as set out in the grid.

3 Now, in the process of how the clinician
4 incorporates that information into a clinical process, we
5 expect that clinician to have access to the literature on
6 the various subjects that are relevant. We expect that
7 clinician to access continuing education capabilities. We
8 provide some of that general education, but we don't expand
9 upon the claims, certainly do not intentionally expand upon
10 any of the claims that are made, that are prescribed in the
11 510(k). If we do, then we expect the FDA to be all over us,
12 and I can assure you no manufacturer finds that a very
13 pleasant experience because the FDA exerts a lot of
14 authority, and the FDA does not accept manufacturers'
15 defying their authority and defying the limitations that--I
16 mean, the 510(k) process is in itself a rigorous process.
17 We are examined at that stage of the regulation.

18 I don't know if this answers the question. I can
19 make available marketing information, but we are under a
20 microscope. Our marketing and sales people, our engineering
21 people, are continually concerned with the issue of is there
22 anything that we are claiming that can bring us into
23 contention with the FDA with respect to are we expanding in
24 any way what we can legally claim about the product. And as
25 I stand here, you know--and I'm the officer for this company

1 that is personally liable--not corporately but personally
2 liable, ultimately, for any expansion of claims that the FDA
3 considers to be inappropriate. And those sanctions in terms
4 of civil money penalties and others are severe.

5 So our claims are set by the 510(k)s under
6 existing regulation, and believe me, both corporately in
7 terms of our personnel and in terms of my position as the
8 ultimate officer for the corporation, I take it seriously
9 because I know whose neck is on the line.

10 Any questions?

11 DR. TALLEY: Mr. Jankelson, Bob Talley. In the
12 Panel's outline where the TMD specific intended uses in
13 legally marketed devices, under sonogram there is a word in
14 place, "interpret." Are you stating to us that your company
15 does not use that word in its marketing of your device for
16 sonographic recordings?

17 MR. ROLAND JANKELSON: I've stated that, yes, but
18 I've drawn a distinction between our device and what I
19 believe to be claims made by a competitor's device.

20 DR. TALLEY: Yes, sir. Secondly, on the
21 kinesigraph listing it states that the device identifies,
22 et cetera, items in here listed, and then, "an
23 interpretation of jaw movements." How do you stand and what
24 is your position on the use of the word in this descriptive,
25 the use of the word "interpretation"?

1 MR. RONALD JANKELSON: I'm going to invite Dr.
2 Robert Jankelson, if he wants to add or correct anything
3 that I say here from his point of view.

4 My answer is that the kinesiograph provides
5 information, provides data, it measures what it is claimed
6 to measure, those parameters that are described in the grid.
7 It does not interpret. It is the clinician's responsibility
8 and obligation to do the interpretation.

9 We are also always concerned that we stay within
10 the requirements of the American Dental Association Seals,
11 and those conditions are very specific. The seal language
12 is very, very clear that the instrumentation is not
13 independently diagnostic, that the instrumentation is to be
14 used only as an aid in the process that the clinician is
15 involved in and that the ultimate responsibility for a
16 diagnosis is with the clinician.

17 So both in terms of the ADA requirements and in
18 terms of the FDA claims, there is no question, in my mind,
19 that we are perfectly consistent, that we are accurate--let
20 me use the word--that we are accurate when we characterize
21 this device as a device that records the information, makes
22 that information available to the clinician in ways that
23 reach levels of accuracy, reproducibility, objectivity that
24 can't otherwise be achieved.

25 What the clinician does with that, and this is not

1 to imply that we are not concerned with what clinicians do
2 with it on a personal level. We are involved in this
3 business because Dr. Bernard Jankelson began the research in
4 this area decades and decades ago. Dr. Robert Jankelson
5 continued that as his life's work. And as a member of the
6 family, I have been available to support the continuation of
7 that work through Myotronics.

8 So certainly we don't detach ourselves on a
9 personal level from how the instrumentation is being
10 utilized by clinicians on a personal level. That's why we
11 are involved because of the value that we feel the
12 instrumentation has and it's capability. That's why we
13 continue to be in business. We have talked about financial
14 interests, and I understand the term, but we're in this
15 business not because this is a financially rewarding
16 activity, not because this company is a great investment for
17 us. We feed this company.

18 So we are concerned with the clinicians'
19 utilization. But in terms of what the Panel is dealing
20 with, we are offering a device that is a measuring device,
21 is a recording device. We make no claims that it is
22 anything other than that, and those claims are prescribed in
23 the 510(k). That regulation is already there.

24 DR. TALLEY: Thank you, sir. That's clear enough
25 for me. Thank you.

1 I do have one comment. I like parallels and
2 analogies. If I were to go out and buy a new airplane
3 tomorrow, I would assume that that airplane meets the
4 regulation requirements for manufacturing and safety. But
5 that manufacturer is not necessarily responsible for
6 determining whether I know how to fly that airplane. That
7 is determined by my ability to achieve a license. The same
8 thing is true of us in dentistry as having a license to
9 practice dentistry, and we assume, and there has to be some
10 relative assumption, that these individuals that would use
11 these instruments have sought appropriate training to use
12 this instrument and to be able to use it as a diagnostic
13 aid.

14 MR. ROLAND JANKELSON: My comment would be, in
15 that regard, that from a sales and marketing point of view
16 for our product, we don't find clinicians waking up one day
17 and deciding that they are going to invest in this type of
18 instrumentation. The clinicians who acquire the
19 instrumentation typically have involved themselves in a
20 lengthy education process to arrive at the point where they
21 have an awareness that the kinds of information that is
22 produced by these technologies are important to what they
23 are doing or what they are trying to do.

24 I understand there are all kinds of ethics in any
25 profession, and we have heard things said over the last

1 couple of days about the dental profession that, in some
2 contexts, could be interpreted as being less than positive.
3 But my experience--and I am an outsider. I am from outside
4 your profession--my experience is that the clinicians who
5 arrive at the point in the development of their interest in
6 this disease are people who do it out of a sense of mission.
7 It's an extremely conscientious, well-meaning group of
8 professionals, and we don't sell instrumentation from the
9 standpoint that you are better off being a TMD specialist
10 than doing other things.

11 My observation is that the group of clinicians
12 involved in this particular field as a primary interest are
13 people who are really sacrificing economic opportunities to
14 do other things in their profession because they are trying
15 to help people.

16 So how the instrumentation is used is entirely in
17 the hands of the clinician. Is it of interest to us
18 personally who are involved in this because of the desire to
19 see progress made in this field and patients helped? Yes,
20 we are very interested.

21 Questions?

22 [No response.]

23 MR. RONALD JANKELSON: Thank you.

24 CHAIRPERSON JANOSKY: Additional discussion by
25 Panel?

1 DR. HEFFEZ: I have a question.

2 CHAIRPERSON JANOSKY: Dr. Heffez?

3 DR. HEFFEZ: As I understand it, your company
4 doesn't make any claims as to treatment decisions regarding
5 the information that is gleaned from the instrument, but do
6 you actually state that in your manufacturing guidelines or
7 labeling guidelines?

8 MR. ROLAND JANKELSON: Yes, because we display the
9 ADA seal, which is an explicit statement of that. If we
10 said anything in our marketing literature or any other
11 labeling, it would be inconsistent, and the ADA also has a
12 regulatory apparatus oversight, so that if we violate the
13 conditions of our seals, which we consider to be very
14 important--

15 DR. HEFFEZ: Do you do that only by virtue of
16 using the seal or do you actually make the statement?

17 MR. ROLAND JANKELSON: Our marketing literature I
18 think in all instances makes that clear. I think anybody
19 speaking as a professional, as a teacher, in any kind of
20 educational setting in which the company has a connection or
21 a sponsorship, also makes that clear.

22 DR. HEFFEZ: But your marketing literature
23 actually states that all of that information that you said;
24 that it was diagnostic, but it was not a sole criteria used
25 in making a treatment plan, et cetera?

1 MR. ROLAND JANKELSON: I think our marketing
2 literature does make that clear. Our marketing literature
3 is explicit with respect to what the instrumentation does.
4 That alone, if the marketing instrumentation does not state
5 or imply or allow room for the conclusion that the
6 instrumentation does something more, I think that's what we
7 do.

8 Am I answering the question?

9 DR. HEFFEZ: You are, but you used the word
10 "think" in there several times, and I am just not clear. Do
11 you or do you not state that?

12 MR. ROLAND JANKELSON: I do state that.

13 DR. HEFFEZ: I can't hear anything.

14 MR. ROLAND JANKELSON: I said I do state that, and
15 thank you for the question.

16 DR. GONZALES: Gilbert Gonzales. We've heard that
17 with class I designation for devices that in addition to
18 labeling restrictions, which are very unusual, also heard
19 from Dr. Gutman that there is an accountability method where
20 design controls can be put on a class I with input and
21 output. That is separate from the labeling, and that's in
22 addition to the basic requirements of class I; is that
23 correct?

24 DR. GUTMAN: That's correct. And if you are
25 interested in exploring that or having us explore that, you

1 could make that recommendation. As this classification is
2 developed, there would be a specific requirement or request
3 that that could be incorporated into the classification.

4 DR. GONZALES: Dr. Gutman, you mentioned or you
5 gave an analogy that I could follow very well, so I will
6 bring it up again because it is helping me in terms of the
7 classification. You used the immunohistochemical analogy of
8 lymphocyte specific antigen, for instance, where it could be
9 used as a data bit or you used the term adjunct or
10 adjunctive piece of information.

11 But then if the same lymphocyte specific antigen
12 were then used specifically to claim a diagnosis; that is to
13 say, if it was used to say this person has lymphoma, then it
14 would go into a different classification. In the same way,
15 if we have a device where there is data bits or basic data
16 being given with no interpretation, but it can be used for a
17 diagnosis, just like the lymphocyte specific antigen versus
18 another device--it's the same device--but now the statement
19 is that it can be used to give a specific diagnosis, in this
20 case myofacial pain or something else, that although they
21 are the exact same devices, they would be different
22 classifications based on the fact that the data plus the
23 interpretation coming from that data is different between
24 the two devices.

25 DR. GUTMAN: That's correct.

1 DR. MOSES: Allen Moses. I would like to address
2 this to Dr. Gutman. If we say that we think that this
3 should be, for example, hypothetically, class I with design
4 controls, do we have to tell you what the design controls
5 are or are you going to tell us what they ought to be?

6 DR. GUTMAN: Well, you are certainly welcome to
7 make recommendations. But to be perfectly honest, the
8 expertise for design control is not in the room. They are
9 other folks. Dr. Alpert is going to bail me out.

10 [Laughter.]

11 DR. ALPERT: That's my job. The issue of design
12 controls is a process, not specific testing. The testing is
13 determined by the company on the basis of what they believe
14 is appropriate in monitoring their device. That's an
15 internal thing to the manufacturer of the device.

16 When we say we want this device to be subject to
17 design controls, what we are saying is that each
18 manufacturer of this kind of device must establish that
19 process as part of their manufacturing.

20 DR. MOSES: Thank you.

21 CHAIRPERSON JANOSKY: At this time, we will take a
22 15-minute break, returning at 10:35.

23 [Recess.]

24 CHAIRPERSON JANOSKY: We are continuing the open
25 committee discussion. It's a continuation of the open

1 committee discussion.

2 [No response.]

3 CHAIRPERSON JANOSKY: Am I reading the Panel that
4 there is no need for any more open committee discussion? I
5 am reading correctly? No. Dr. Moses?

6 DR. MOSES: Discussion?

7 CHAIRPERSON JANOSKY: Yes.

8 DR. MOSES: Oh, I would like to discuss.

9 I think that in the matter of interpretation of
10 sonographic devices I feel that probably it's based on sound
11 scientific literature. I believe in our packets we were all
12 given the literature. I believe that it still it's an
13 adjunct in the sense that when it's given it's given in the
14 same sense of the information. The doctor still has to
15 decide whether to use it or not.

16 Yes, the impact of a false positive and a false
17 negative are there, but the impact of the false positive and
18 the false negative is there based on the information that
19 the doctor gets as well. Once the doctor makes the
20 diagnosis, the possibility of false positive or false
21 negative is there.

22 So I am wondering how you would feel, Dr. Gutman,
23 as to what the differentiation, in your mind, could be or
24 should be or do you have to know what we think that
25 sonography alone is first before you make--or do you give

1 advice on this?

2 DR. GUTMAN: Well, I think it would be appropriate
3 to consider both claims--to approach this from a hierarchial
4 point and see if you come out to a different decision for
5 the tool. One of the things you have to address, even for a
6 more general claim, not for an in interpretative claim, but
7 for a claim that it measures the output and then is
8 interpreted, not making the next step.

9 The challenge to you will be to decide what is the
10 appropriate level of regulation. The appropriate level
11 could be a class I exempt, it could be a class II, it could
12 be a class II, and then I think you ought to reapproach it
13 when you get to the interpretative whether that is different
14 or not. In both cases and, again, you are not bound by
15 this, but what we use in my shop is we use the strength of
16 the signal and whether the information actually tips you
17 into making a diagnosis or not, whether that marginal piece
18 of information stands alone or whether it is buried in a sea
19 of background, and that's a professional judgment you guys
20 have got to help us with because I honestly don't know.

21 DR. MOSES: Thank you.

22 DR. REKOW: This is Diane Rekow. I think my
23 opinion, from what I have read and what I have heard, is
24 that there is little question that the two devices, either
25 one of them or both of them together, accumulate data that

1 may or may not be available from other less-sophisticated
2 means. It certainly does, though, increase the amount of
3 data that you can subsequently, post-process, and play
4 around with and decide what you want to do for different
5 analysis.

6 . The thing that perplexes me, though, is some of
7 the impact of the false positives and false negatives that
8 Dr. Gutman has suggested, and I am also perplexed about
9 hearing and reading so many times the fact that clinicians,
10 it appears, seem to be trading to certain motion
11 trajectories, for instance, and I am not sure that there is
12 a clear-cut difference and differentiation between what is a
13 normal or asymptomatic joint and ones that are pathological
14 and painful, and I think that that's the thing that hangs me
15 up the most.

16 If we could clearly say that this is normal and
17 this is not, it would be a much easier issue, and maybe that
18 is something that the clinicians are doing that is not in
19 the information. But as I read the grid, I am concerned
20 about the thing that says "and treatment" "and
21 interpretation," and those are the things that still perplex
22 me about what I am reading and my decision process.

23 DR. MOSES: I would like to actually discuss that
24 and address that, in that it's a very interesting disease.
25 We are dealing in stress diseases, in general, here. If you

1 think in the bigger terms, for example, in Scientific
2 American this month there was an article on back problems,
3 and what they said is that the more specific the testing
4 got, the more pathology they found, but that there is no
5 reflection of pathology and people complaining.

6 . It really sort of duplicates the study by Horale
7 in the fifties, where he took two matched control groups and
8 found that, based on signs and symptoms with back problems,
9 he couldn't tell the difference between one group and the
10 other group. The only difference was that the noncontrol
11 group was complaining about pain.

12 And so really what we deal with in this situation
13 is we are dealing with a group of patients who are self-
14 selected. They say that they've got the problem, and so we
15 are getting into semantics again. It gets into the
16 difficulty that was actually caused in '91, when Dworkin at
17 an NIH conference defined it as an illness based solely on
18 the patient's subjective feeling of feeling poorly, and
19 there's plenty of people using that, and the psychology
20 profile that goes with that to make the diagnosis.

21 Today, the literature says the psychological
22 profile is not a reflection of treatment outcome. So these
23 things can all go. What we are dealing with is a
24 symptomatic patient who is self-selected saying I've got the
25 problem and then the doctor looks at it and with this

1 information he could say, "Well, it's always in your head,
2 but there are physiological parameters by which I can treat
3 if you understand and you think that this is going to be
4 appropriate for you," and, of course, the answer then is--
5 the next step is that this kind of treatment or this kind of
6 diagnostic equipment, this kind of diagnostic aid offers the
7 opportunity for noninvasive treatment, and the end result is
8 not based on normal or abnormal, but it's based on how close
9 to ideal can you get.

10 There's another important aspect to this, and that
11 is how close and how specific do you get? If Dr. Cooper
12 treats TMD in the bigger sense, based on his conception of
13 what it is, that's different than if I try and take it to
14 the next level of myogenous problem, and I'm looking very
15 carefully at that electromyograph to see how close I can get
16 those muscles to optimal performance. But the disease
17 specificity that you choose to treat is the variable of how
18 you use the equipment.

19 But in any case, we are using the equipment to
20 treat as close as we can to ideal, and the difference is
21 that the next patient who walks in the door could be
22 asymptomatic and have a panex with more arthritic-looking
23 joints, and if you do the electromyography they will be off
24 the chart.

25 DR. REKOW: Do we know what ideal is? Is that

1 clearly available information?

2 DR. MOSES: Yes, to the extent that this has been
3 done, too. For example, I would refer you to Arthur J.
4 Miller's book, Cranial Mandibular Muscles Form and Function.
5 He wrote it in 1991. The parameters that they are treating
6 to, for example--in fact, Dr. Jankelson, I believe, did the
7 study and presented it in Florence in about 1989 and said
8 that muscles in correct maximal occlusion have greater
9 electromyographic activity than muscles that are in a bite
10 that's dysfunctional.

11 DR. REKOW: But does that make the pain go away?
12 Does that make the patient better?

13 DR. MOSES: Can't tell. Can't tell. If it's a
14 myogenous problem, it did, which gets into another
15 diagnostic modality. If you are doing it noninvasively,
16 perhaps this diagnostic modality is diagnosed by ruling out,
17 diagnosed by treatment. This happens in medicine a lot.

18 In fact, typically, a patient like this, many of
19 these patients will start out with a neurologist, and the
20 neurologist will do his thing. It's not his problem. He
21 may refer the patient to an ENT. Somewhere along the line,
22 by a process of elimination, they get to the dentist. And
23 he does his thing, and maybe he's right and maybe he's
24 wrong.

25 But when we have these measurable parameters to go

1 to, we have standards by which when we're done to say we've
2 done what we can do, and we also don't treat unnecessarily.
3 If the situation looks such that there is no joint problem
4 and no muscle problem or the muscles are performing as
5 perfectly as they can, it has happened that I've said to the
6 patient, you know, you may need counseling.

7 DR. REKOW: Can I play devil's advocate?

8 DR. BURTON: Let me interject one thing here. I
9 guess I'm still very concerned here. I've obviously been
10 concerned about some of the labeling issues and how this is
11 used. But, again, you keep making a statement now that we
12 are going to use this because this is going beyond giving us
13 a set of data. We're going beyond that and saying now we
14 know what ideal is. Ideal is equal to good, but is good and
15 ideal being the patient being symptom free or is it we are
16 treating it to a set of numbers? What I heard out of the
17 last statement was, Well, I know what ideal is. I'll put
18 you at ideal and, hopefully, you'll be better.

19 DR. MOSES: That's the nature of stress diseases.

20 DR. REKOW: I was going to hypothesize a similar
21 question. Suppose you have a patient that you, with all of
22 the diagnostic stuff that is possible in the entire world,
23 you are able to determine that because of the path of the
24 motion that patient is not--I mean, that's the only thing
25 that is potentially an issue; that for some reason the

1 patient opens and closes differently than they should. If
2 you put them back to an ideal, whatever ideal is, motion
3 trajectory and velocity, will that patient get better
4 always?

5 DR. MOSES: If I have achieved that, they are
6 better. The question you are asking me I hear is are they
7 going to be pain free always.

8 DR. REKOW: Yes.

9 DR. MOSES: I can't answer that. Dr. Cooper is an
10 excellent clinician. I've seen his practice. I've spent an
11 enumerable amount of time with him, and I think his results
12 show that he only got 70 percent of them--what he
13 categorized as 70 percent success. Nobody gets 100 percent.
14 There's no guarantees.

15 DR. REKOW: Well, I understand that they wouldn't
16 get 100 percent, but you can guarantee that the major
17 proportion of the patients would get better and stay better,
18 would be pain free and stay in that trajectory after you
19 correct it to that position.

20 DR. MOSES: Oh, yeah, but I'm qualifying better to
21 be a physiologic better, not necessarily a pain better. I
22 can't guarantee the pain better, no one can.

23 DR. HEFFEZ: May I ask a question?

24 MS. SCOTT: Yes, please.

25 DR. HEFFEZ: I have difficulty in saying in one

1 breath that the symptoms of the patient are not necessarily
2 related to objective evidence of "disease" or "signs of
3 disease" and on the other side saying that we are trying to
4 match an ideal. So I don't think you can say that.

5 I think it's realistic to say that there are some
6 unknown factors that we're not certain of that are involved
7 in the process, and having not identified them, patients do
8 improve either with time because of progress of the disease
9 or possibly related to the treatment modality that we
10 selected. But to say that we're going to match an ideal,
11 but in the same breath say that a person may have terrible
12 masticatory muscle EMG findings or gross changes in the--
13 radiographic changes or MRI changes and the patient be
14 asymptomatic, one has to realize that there are other
15 factors, and we haven't been able to identify what ideal is
16 and, clearly, God didn't make ideal human beings.

17 [Laughter.]

18 DR. MOSES: Gee, I certainly would agree with
19 that. I wouldn't take issue with that.

20 DR. HEFFEZ: So I think that the best way to look
21 at this whole process is, and I can't, unfortunately,
22 analyze everybody's face when I'm speaking, but I think it's
23 best to look at the process and study the process first with
24 these two devices as purely diagnostic devices and then
25 tackle the issue whether they can be used for treatment.

1 And if we broke it up I think that we'd see a better or an
2 easier outcome from all of our discussions. That's all.

3 DR. TALLEY: I would like to accentuate that we
4 seem to be, again, digressing back to other than the issue
5 of this Panel in looking at philosophical use of the devices
6 as opposed to their specific recording and calibrating
7 issues that we are here for. I, unfortunately, feel we
8 could probably spend the next week here at this Panel
9 discussing the issues before us that are being brought up on
10 philosophy.

11 The use of the device as a treatment tool, we seem
12 to be shifting to that analogy, and I don't believe that is
13 the implication here or the issues with regard to these
14 devices. That is all I have to say.

15 CHAIRPERSON JANOSKY: Additional committee
16 discussion?

17 [No response.]

18 CHAIRPERSON JANOSKY: At this time I propose that
19 we start working through the general device classification
20 questionnaire if everyone is comfortable with us taking on
21 this phase.

22 Could we have some assistance from FDA staff?

23 DR. MOSES: A procedural question here. Are we
24 going to submit one vote per group? In other words, is
25 Question 1 going to be voted on by each of us separately and

1 tallied or are we going to vote on Question 1 first? How
2 does this procedure work next?

3 MS. SCOTT: Let me try to clarify this. The way
4 that the procedure that we utilize is the questionnaire and
5 supplemental data sheet are used to aid the Panel in coming
6 to a recommendation. So the Panel fills out the
7 questionnaire. You don't vote on each question. You fill
8 out the questionnaire and the supplemental data sheet, and
9 then you vote on your final recommendation. A Panel member
10 will make a motion or move to recommend a particular class,
11 someone will second it, and then we will have the final
12 vote.

13 We also have Ms. Marjorie Shulman from our Program
14 Operations staff who can assist us in answering questions
15 that the Panel may have as we proceed through the
16 classification questionnaire and supplemental data sheets.
17 We will fill these two forms out for each device separately
18 and vote on each device separately.

19 So Dr. Janosky will let us know which device we
20 will start on.

21 CHAIRPERSON JANOSKY: I propose that we start with
22 the jaw-tracking device. The overhead contains a general
23 device classification questionnaire; is that correct?

24 MS. SHULMAN: Yes. As a matter of just
25 housekeeping, if everyone could please write their names on

1 the top of their sheet.

2 Just a quick reminder of the instructions. A
3 medical device should be placed in the lowest class which
4 will provide adequate controls to reasonably assure the
5 safety and effectiveness of the device. So when we start
6 out with Questions 1, 2, and 3, also they pertain to the
7 degree of risk of the device and can be answered broadly.

8 MR. LARSON: Just another housekeeping question.
9 We are going to be working on several devices. Will we have
10 additional copies of this form that we will be using?

11 CHAIRPERSON JANOSKY: Yes, they're forthcoming.

12 Ms. Shulman, is it reasonable to read each of the
13 questions?

14 MS. SHULMAN: Yes, please.

15 CHAIRPERSON JANOSKY: Do you prefer to do that or
16 do you--

17 MS. SHULMAN: It's up to you. I can do it or
18 would you like to do it?

19 CHAIRPERSON JANOSKY: Please.

20 MS. SHULMAN: Should we start with the generic
21 type of device?

22 CHAIRPERSON JANOSKY: Yes.

23 MS. SHULMAN: And that was, you said--

24 CHAIRPERSON JANOSKY: Jaw tracking is what we were
25 going to start with.

1 MS. SHULMAN: The first question: Is the device
2 life-sustaining or life-supporting?

3 If you want to start one at a time, that is fine.

4 [Chorus of nos.]

5 CHAIRPERSON JANOSKY: No. Okay.

6 DR. ALPERT: One comment and that is that one of
7 the things you need to determine is what claim for these
8 devices are you classifying because it's the device claim
9 complex that's actually being classified. So I think one of
10 the things you may want to say about jaw tracking, and we
11 brought some extra overhead for that purpose, is what are
12 the claims? And you have that on the grid. Are those the
13 claims? Do you think all of them belong together or do you
14 want to consider them separately? That's one of the
15 questions you have to ask yourselves before you can then
16 fill out the questionnaire because it's on the combination.

17 CHAIRPERSON JANOSKY: No. Please, either you or
18 Dr. Runner. I had heard diagnoses; is that correct?

19 DR. RUNNER: As it states on the grid, the claims
20 that we have seen are identify freeway space, identify
21 mandibular rest position, record relationship of the
22 mandible to the base of the skull, and then as a
23 subcategory, interpretation of jaw movements--

24 DR. MOSES: I would like to suggest that that be a
25 third item be record jaw movement is really what it does.

1 DR. RUNNER: Okay. We can put that as another
2 one, record jaw movement because we have--

3 DR. MOSES: No, I am suggesting that, in my
4 opinion, as a user, it doesn't interpret the movement. It
5 records the movement. Now I understand that this is your--

6 DR. RUNNER: But I think what you need to do, I
7 mean, I agree you can put record jaw movement, but you might
8 want to consider giving a classification for that particular
9 claim because that's something we have seen. For example,
10 if you wanted to give a classification for each one of
11 these, and maybe some of them would all be class I claims,
12 but maybe another would be a class II or class III claim
13 because those are claims we have seen.

14 And as Dr. Alpert mentioned before, if you don't
15 give a classification for potential claim, then it would
16 automatically go into class III at a later date if that
17 claim came into us.

18 DR. MOSES: What I am suggesting is that maybe we
19 ask the manufacturer if, in fact, their labeling claims to
20 interpret.

21 DR. RUNNER: But what I'm saying is that we have
22 seen labeling that claims to interpret. That's why it's on
23 the grid.

24 DR. MOSES: Okay. I understand. Okay. Add
25 record. I'd like to see that. Thank you.

1 DR. BURTON: The suggestion then would be that we
2 separately consider--

3 DR. RUNNER: If that's what you wish.

4 CHAIRPERSON JANOSKY: Are we combining by the
5 terminology as identify, record, and interpret, irrespective
6 of what it is? So the claims for the identification--

7 MR. LARSON: I think we'll find our job easier if
8 we take interpret out for the time being, deal with that,
9 and then come back to it.

10 CHAIRPERSON JANOSKY: Right. That's what I am
11 saying. Should we break them up by the terms as to what
12 these behaviors are or what they are?

13 So, first, let's deal with identification and
14 record. Are we in agreement that those two can be combined?
15 Is that correct?

16 DR. MOSES: Which two? The first two? Oh, sure.

17 CHAIRPERSON JANOSKY: So the devices that identify
18 and record, those can be combined. So what we are now, for
19 the generic type of device, it's jaw tracking for
20 identification and recording. Yes. And then we'll deal
21 with interpretation as a totally different form. Any
22 comments on that suggestion? Mr. Larson?

23 MR. LARSON: I think that's a good suggestion, but
24 also then we need to go on to the last phrase of the
25 intended use in the grid, and that is in diagnosis and

1 treatment of TMD/orofacial pain.

2 CHAIRPERSON JANOSKY: Right.

3 So, currently, we are dealing with identify and
4 record jaw movement for diagnoses.

5 DR. TALLEY: That will be on this form.

6 CHAIRPERSON JANOSKY: That is correct.

7 DR. TALLEY: We are going to use a separate form--

8 CHAIRPERSON JANOSKY: For when we deal with
9 interpretation.

10 So, so far, jaw-tracking devices we have broken
11 them up into two different purposes; one for identification
12 and recording, the other for interpretation, where
13 interpretation, if I am not overstepping my bounds, might
14 also include identification and recording because, clearly,
15 you have to record to interpret on some level.

16 So if we continue down, we are on Question 2.

17 MS. SHULMAN: Two: Is the device for a use which
18 is of substantial importance in preventing impairment of
19 human health?

20 Do you want to start over here again? Mr.

21 Larson, do you want to start over here?

22 MR. LARSON: Let someone else start this time.

23 DR. TALLEY: Bob Talley, no.

24 MS. SHULMAN: Do you just want to go in order?

25 CHAIRPERSON JANOSKY: How about if there's any

1 disagreements; it that reasonable?

2 MS. SHULMAN: That's fine. Is there any
3 disagreement?

4 DR. GONZALES: Not necessarily disagreement, but
5 just for the purpose of discussion, obviously, if you have
6 the disease, the way it's written is the device for use
7 which is of substantial importance in the prevention and
8 impairment of human health? The key I guess here is in
9 preventing impairment of human health. Because substantial
10 importance, obviously, the individual who has it, it's of
11 substantial importance.

12 I know I am nitpicking this, and I also know that
13 the response is going to be no, but it's just the wording
14 that makes you think twice and three times about the
15 direction we are going with this because it could be
16 interpreted by some, but I suppose this group is going to go
17 with no, and I am going with no as well.

18 DR. BERTRAND: I'm not so sure I'm going with no.
19 I might say yes because we are working with patients who
20 think they have something going on, and we're trying to do
21 something to prevent further impairment of health. If there
22 is no reason to use something for future impairment of
23 health, why are we even using it?

24 DR. GONZALES: That's the recurring thing that,
25 with the wording, the way it's stated, that keeps coming up.

1 My tendency is no, but I could see the other side of the
2 story here, depending on whether you have the disease or
3 not.

4 DR. MOSES: Maybe the question should be is the
5 device used. Because clearly they are referring to the
6 device.

7 DR. TALLEY: Madam Chairman, may I reverse my no
8 to a yes?

9 DR. ALTMAN: But in and of itself, the device is
10 not preventing health, right? It's not preventing in and of
11 itself because it's not going to be used by itself.

12 DR. TALLEY: But it's an important device.

13 MS. SCOTT: Could I remind everyone when you make
14 comments to speak directly into the microphone so that the
15 transcriptionist can hear you and also so that Dr. Heffez
16 will hear your comments. Thank you.

17 CHAIRPERSON JANOSKY: Is it possible to get some
18 clarification as to the terminology used in No. 2?

19 MS. SHULMAN: Yes. One second.

20 CHAIRPERSON JANOSKY: Dr. Alpert or Dr. Gutman,
21 Dr. Runner?

22 DR. GUTMAN: This is a tough question, but the
23 issue is not the device, but the information and the way the
24 information is being used. So that is what is on the table
25 is, is the information generated by this device of

1 substantial importance in preventing impairment of human
2 health. I don't know how else to phrase it.

3 DR. ALPERT: The language in the form is a little
4 old, but the concept is one that's also captured in FDAMA in
5 saying if a device were to be placed into class I, but be
6 for a use that is considered to be important in the
7 prevention of significant disease--or the words that are on
8 the form, and I'm not repeating them properly--you can place
9 something in class I, but reserve it and require premarket
10 notification on that criteria. So the criteria of being a
11 use that is of substantial importance in preventing
12 impairment of human health has an impact on the kinds of
13 controls, even the kinds of general controls, that you might
14 want to place around that device. And you are going to get
15 a chance a little bit further down to talk about special
16 controls.

17 But the issue here is, is there a serious risk to
18 the health of the patients that is impacted by the use of
19 this product. That is what the question is asking.

20 DR. GONZALES: That's a different question.

21 DR. MOSES: That's a no.

22 DR. GONZALES: And if that's what you are asking,
23 then no. If the question is importance and prevention,
24 we've heard information about the possibility of using the
25 information for preventing problems in the future, although

1 it's weak, and as far as importance, that's subjective in
2 terms of the patient. But the way you've just worded it, if
3 in fact that's the wording, then it's no because we're
4 talking about--it's a different question.

5 DR. ALTMAN: It seems to me that it's still no
6 because we established early on that we didn't have ideal
7 research, clinical studies that said that using this
8 particular device made a difference, and Dr. Moses even said
9 that he could use information, but he couldn't guarantee
10 that it was going to change the person's health. He can
11 move it to ideal. So it's not that I don't think it's
12 important, but I still think that it's no the way that this
13 is worded.

14 DR. ALPERT: The issues are, again, these are the
15 kinds of issues that we struggle with constantly, and let's
16 put the wording back up, Sandy. The issue is substantial
17 importance in preventing impairment of human health. We are
18 talking about, and then we have the next is the potential
19 for unreasonable risks.

20 Again, we are talking, when we talk substantial
21 impairments and preventing impairment of health, that if you
22 use--I didn't write the form, you can tell.

23 The words are taken out of the statutory language
24 that deals with how we determine the right kinds of
25 controls. It's trying to capture risk. It's trying to

1 capture the risk faced by patients with a disease or
2 condition and the risk that they, therefore, face when this
3 product is being used. The words are not ideal. They are
4 not.

5 So if you look at the kinds of questions, the
6 question is, is it life-supporting, life-sustaining, and
7 then if it's not, is it still highly important in patients
8 at significant risk for impairment of their health. That's
9 the kinds of context that's being framed by the words.

10 We would welcome, after we are done with this, any
11 comments on about how to improve the forms are vastly
12 welcome because we are going to have to redo the forms
13 because we have a new law. So we are going to get to do
14 that. The form is, as you have pointed out, not hard and
15 fast. It's a working document. If you want to make
16 caveats, make your caveats on this process because this is
17 process. This is a work sheet. It's not statutory. It's a
18 work sheet that helps us get to the statutory obligation.

19 We tried to capture it. We didn't do a good job,
20 I can tell.

21 DR. GONZALES: Based on your use of the term
22 "risk," and that's the direction of this question, then it
23 would be no. I would agree now with the wording, but it
24 would have to be reworded.

25 DR. ALPERT: I agree.

1 DR. TALLEY: With all due respect, the word "risk"
2 is not in No. 2.

3 DR. ALPERT: That's correct.

4 DR. TALLEY: And if we look at that and break this
5 statement or question down, is the device for a use, not the
6 device is of substantial importance, but is it's use of
7 substantial importance as a diagnostic tool. Diagnosis is
8 of substantial importance in preventing impairment of human
9 health. Therefore, if it aids in the diagnosis of a certain
10 disease entity, whatever we want to identify TMD to be, then
11 I see it as being of substantial importance, even though
12 it's one tool in a vast number of tools in diagnostic
13 regimen.

14
15 DR. REKOW: Doesn't that presuppose you know what
16 normal is?

17 DR. TALLEY: Are you asking me?

18 DR. REKOW: To be a diagnostic tool, don't you
19 need to know that it can differentiate one group of patients
20 from another, that you know that?

21 DR. BERTRAND: We don't really know what the
22 ideals are, but we are using this to record data in a group
23 of patients. So it does have a use that potentially may be
24 beneficial or if ever all parties get whatever controlled
25 trials performed, we may have a final answer. But in the

1 meantime, it is being used with a group of patients, and
2 data is being collected.

3 DR. REKOW: But is it substantial? That's the
4 tricky word.

5 DR. ALPERT: I want to make one more comment, and
6 then I'm going to get out of your way again. The fact that
7 the product is in the diagnostic versus the therapeutic
8 category for us, in terms of how we sort of look at the
9 world of devices, is separate from whether the claim is made
10 as an independent diagnostic, and I think we are sometimes
11 confusing the two.

12 The fact that it has a use in diagnosis makes it,
13 to us, diagnostic, although the claim may not be this is an
14 independent diagnostic, and I think that subtle
15 differentiation is critically important in this particular
16 setting because, although they are in the diagnostic
17 category, we don't require each product going to market to
18 be independently--it has to contribute toward a diagnosis,
19 but it doesn't have to independently provide the make or
20 break for a diagnosis, and I think we get ourselves into the
21 concept of saying this is diagnostic, meaning it's telling
22 us what the patient has as opposed to this is used as part
23 of the diagnosis.

24 When we say it's in the diagnostic category, we
25 mean it's useful as diagnosis moves forward. The threshold

1 is not that it be sufficient by itself.

2 CHAIRPERSON JANOSKY: Should we go to Question 2?

3 Maybe a show of hands for no.

4 [Show of hands.]

5 CHAIRPERSON JANOSKY: Show of hands for yes?

6 [Show of hands.]

7 CHAIRPERSON JANOSKY: So if we go by pure

8 majority, how about if we put no and keep working.

9 DR. HEFFEZ: [Via telephone.] For the record I
10 was no.

11 [Laughter.]

12 CHAIRPERSON JANOSKY: Thank you for piping in
13 there.

14 DR. HEFFEZ: I'm with the majority.

15 CHAIRPERSON JANOSKY: So we're on Question 3?

16 MS. SHULMAN: Question 3: Does the device present
17 a potential unreasonable risk of illness or injury?

18 DR. MOSES: Suggesting no.

19 MS. SHULMAN: Should we just go were there any
20 yeses?

21 CHAIRPERSON JANOSKY: Okay. So no to Question 3?

22 MS. SHULMAN: No.

23 CHAIRPERSON JANOSKY: Question 4?

24 MS. SHULMAN: Did you answer yes to any of the
25 above three questions? No. So we are on to No. 5.

1 Is there sufficient information to determine that
2 general controls are sufficient to provide reasonable
3 assurance of the safety and effectiveness? Now, the general
4 controls are from yesterday's training on the sheet I gave
5 you.

6 CHAIRPERSON JANOSKY: Can you remind us what those
7 general controls are.

8 MS. SHULMAN: Yes, I'll get that real quick.

9 CHAIRPERSON JANOSKY: Do we have it somewhere that
10 we can just look at it?

11 [Pause.]

12 CHAIRPERSON JANOSKY: Dr. Shire?

13 DR. SHIRE: Hi.

14 CHAIRPERSON JANOSKY: Jaw tracking about
15 kinesiology place or the generic type, and we are studying
16 for, if I remember correctly, for recording and--I lost my
17 wording. Identifying and recording.

18 We are currently on Question 5, and we were
19 getting a clarification as to general controls.

20 MS. SHULMAN: General controls include a
21 registration, recordkeeping, good manufacturing practices,
22 restrictions against band devices, prohibition of
23 adulterated or misbanded devices and 510(k) can be a general
24 control, which you may vote on later if that's the way you
25 decide to go--class I.

1 CHAIRPERSON JANOSKY: So returning to Question 5:
2 Is there sufficient information to determine that general
3 controls are sufficient to provide reasonable assurance of
4 safety and effectiveness?

5 I hear a comment of yes.

6 DR. MOSES: I'm suggesting yes.

7 MS. SHULMAN: Were there any no's?

8 CHAIRPERSON JANOSKY: Is any Panel member in
9 disagreement?

10 [No response.]

11 CHAIRPERSON JANOSKY: So yes is the answer to No.
12 5. Dr. Hefez, I am taking it that you are agreeing with
13 the yes?

14 DR. HEFFEZ: Yes.

15 CHAIRPERSON JANOSKY: So, if yes, classify in
16 class I.

17 MS. SHULMAN: Class I.

18 No. 6: Is there sufficient information to
19 establish special controls to provide reasonable assurance
20 of safety and effectiveness?

21 CHAIRPERSON JANOSKY: Do we need to go on to
22 Question 6 or we have stopped because we have led to our
23 classification; am I correct? Yes. So my understanding is
24 we are then--

25 MS. SHULMAN: So then Question 6--

1 DR. ALPERT: FDAMA didn't--we don't, the forms,
2 these are forms that were developed before the FDAMA '97 was
3 passed. On the basis of FDAMA '97, although generally you
4 would be asked about 510(k) or no 510(k), according to this
5 form, the threshold for being able to retain a class I
6 device under 510(k) has changed.

7 That's what I was speaking to before, and that is
8 that you may place something in class I and then determine
9 that either it, itself, poses risk, and there are some
10 devices where we have retained them because they introduce
11 energy into the body and felt that there needed to be
12 oversight.

13 We needed to see the data before products
14 introducing energy into the body went into the marketplace,
15 even though, on the basis of all of our understanding of the
16 uses and so forth, they were class I. So the first thing is
17 whether the device poses significant risks to the patients
18 and the second is we are back to the wording in Question 2,
19 which was is it of significance importance in preventing
20 harm, preventing impairment of health?

21 And if you believe that there are aspects of the
22 device that would render it of a risk that needed to be
23 assessed, there were aspects of the device, although it
24 could be in class I, that needed a premarket evaluation
25 because of a concern about impairment of health or a risk of

1 the product, then you can ask that it be retained in 510(k).
2 Absent that, all class I devices are exempt from premarket
3 notification by statute.

4 So putting it in class I now you have to ask
5 yourselves is there a reason to need the premarket review.

6 MS. SHULMAN: Correct. And that's on the
7 supplemental sheet.

8 DR. ALPERT: Right, and it's a higher threshold.
9 But I wanted to make sure the context of that was there. It
10 seems like we're asking a class II question, we're not.
11 We're not saying that this requires special controls. It's
12 a different type of question.

13 CHAIRPERSON JANOSKY: Thank you.

14 MS. SHULMAN: So we do answer Question 6, correct?

15 DR. MOSES: No.

16 CHAIRPERSON JANOSKY: How about Question 11(a), do
17 we need to--

18 MS. SHULMAN: Yes, 11(a). It's on the back of the
19 form because Question 7 is the special controls. Questions
20 8 and 9 only apply to performance standards, and Question 10
21 is only for a class III device.

22 Question 11(a): Can there otherwise be reasonable
23 assurance of its safety and effectiveness without
24 restrictions on its sale, distribution or use, because of
25 any potentiality for harmful effect or the collateral

1 measures necessary for the device's use?

2 This is actually the prescription question.

3 DR. MOSES: Recommend no.

4 CHAIRPERSON JANOSKY: We have a recommendation of
5 no. Any Panel member in disagreement?

6 [No response.]

7 CHAIRPERSON JANOSKY: What does that mean? If we
8 say no, does that mean it still needs a prescription?

9 MS. SHULMAN: Correct. If we say no, we go to
10 11(b) and then we identify the restrictions.

11 CHAIRPERSON JANOSKY: So, again, in agreement for
12 no for 11(a).

13 11(b)?

14 MS. SHULMAN: 11(b): Identify the needed
15 restrictions. The first one: Only upon the written or oral
16 authorization of a practitioner licensed by law to
17 administer or use the device.

18 The second one: Use only by persons with specific
19 training or experience in its use.

20 The third: Use only in certain facilities, and
21 then there is an "Other."

22 I don't know if we want to vote on them one-by-
23 one?

24 CHAIRPERSON JANOSKY: Is there a recommendation?

25 DR. TALLEY: I'll speak up. I would recommend

1 that the first item and the second item be checked and that
2 use facilities and other be not included.

3 DR. BERTRAND: I would agree with that.

4 DR. REKOW: Does that mean you could have somebody
5 that can--do they necessarily both need to be employed? It
6 makes a difference if it's an and or an or. I'm
7 uncomfortable with an "or."

8 DR. BURTON: I would disagree. I would just limit
9 it to the first block. I'm not really personally
10 comfortable with a lot of devices. I think we have all seen
11 a lot of changes lately in dental practice acts, but use by
12 persons with specific training or experience in its use, I'm
13 not exactly sure that that's an adequate restriction in its
14 usage.

15 DR. REKOW: I wouldn't mind if an assistant were
16 doing it under a licensed dentist's direction, but I'm
17 uncomfortable with somebody doing it without the dentist
18 having some responsibility for what's going on.

19 DR. BURTON: And you see the first block,
20 basically, addressed that because it's only upon the written
21 or oral authorization of practitioners. So if you had
22 someone in your office utilizing that under your guidance,
23 that falls under that first block.

24 DR. GUTMAN: Let me clarify that. Usually when
25 you check two, you are suggesting that one is implied and

1 that one isn't enough; that you can't just be licensed. You
2 have to have some kind of special experience and training.
3 So two is actually generally thought of as more stringent
4 than one. It's not thought of as a way to download to a
5 dental hygienist or a medical office--a dental office
6 assistant.

7 DR. TALLEY: Dr. Gutman, Bob Talley. Am I correct
8 in the assumption then that if you check one and two, they
9 are not mutually exclusive? It's not one or the other, it's
10 they are both in effect?

11 DR. GUTMAN: That is correct. You would have to
12 have both qualifications.

13 DR. TALLEY: That was the reason I--

14 DR. GUTMAN: The problem with No. 2 is that it's
15 often difficult to use because defining what the appropriate
16 level of experience is often an educational practice issue
17 that goes a little bit at the edge of our regulatory
18 authority. We have used this. We have invoked it when we
19 thought it was really necessary, but it's not, and Nancy can
20 correct me or Marge can correct me if I am wrong, it's not
21 commonly used.

22 DR. TALLEY: but if I understand that correctly,
23 that person listed in Item 2 still has to operate under the
24 written or oral authorization of the licensed practitioner;
25 is that correct?

1 DR. GUTMAN: One presumes actually that it is the
2 practitioner who has got special training.

3 MS. SHULMAN: That is correct.

4 DR. TALLEY: Yes. So I recommend positive on the
5 first two is my recommendation.

6 DR. MOSES: I'd like to discuss that in terms of
7 two being stringent because there is no recognized training,
8 but someone in your office can certainly do it under one,
9 and the idea that all of a sudden we have to have authorized
10 training programs or that the manufacturer is responsible
11 for them may become prohibitive because we, basically, we're
12 dealing--that's an ideal, but basically we're dealing with
13 equipment that is very safe.

14 It seems to me, worst-case scenario, they get
15 information that's not effective, but it's certainly not
16 going to harm the patient. My point being I am comfortable
17 with one checked and not one and two.

18 CHAIRPERSON JANOSKY: Those saying one and two
19 should both be checked, if you could please show by show of
20 hands--one and two.

21 [Show of hands.]

22 CHAIRPERSON JANOSKY: One? And Dr. Hefvez?

23 DR. HEFFEZ: Same.

24 CHAIRPERSON JANOSKY: Was your hand up?

25 DR. HEFFEZ: Yes.

1 CHAIRPERSON JANOSKY: Thank you. And those saying
2 only the first one needs to be checked?

3 [Show of hands.]

4 CHAIRPERSON JANOSKY: One, two, three, four?

5 DR. LARSON: I'm not voting.

6 CHAIRPERSON JANOSKY: You're not voting. Three
7 saying only the first one should be checked and one was
8 saying both of them should be checked, am I correct? I sort
9 of lost track of my tally here.

10 Those saying that only the first one should be
11 checked in response to Question 11(b) would you please raise
12 your hands.

13 [Show of hands.]

14 CHAIRPERSON JANOSKY: One, two, three, four.

15 And those saying one and two should be checked in
16 response to Question 11(b)?

17 [Show of hands.]

18 CHAIRPERSON JANOSKY: Two, and Dr. Heffez. So
19 four to three, am I correct?

20 DR. MOSES: That's the way it looks.

21 CHAIRPERSON JANOSKY: So if we go by majority, we
22 will only check one, 11(b), Box 1.

23 MS. SHULMAN: Correct.

24 CHAIRPERSON JANOSKY: Now we need to move to the
25 supplemental data sheet.

1 Generic type of device, we can copy that from what
2 we had just said on the classification questionnaire.

3 Advisory Panel, yes.

4 Is device an implant? Is device an implement, no?

5 Does anybody disagree?

6 [No response.]

7 CHAIRPERSON JANOSKY: Just making sure. One never
8 knows.

9 We are on Question 4, then.

10 MS. SHULMAN: Question 4: Indications for use
11 prescribed, recommended, or suggested in the device's
12 labeling that were considered by the Advisory--I am sure
13 that is supposed to say Panel.

14 CHAIRPERSON JANOSKY: So what we had said
15 previously was the identification and recording. Is that
16 what you were looking for here?

17 [No response.]

18 CHAIRPERSON JANOSKY: Do you want more specific
19 than that or is that sufficient?

20 MS. SHULMAN: Let me we ask the division--

21 DR. GUTMAN: I think that's specific.

22 MS. SHULMAN: That's specific enough he said.

23 CHAIRPERSON JANOSKY: That is specific enough?

24 MS. SHULMAN: Yes.

25 MR. LARSON: For identification and recording.

1 MS. SHULMAN: Was that of jaw movement?

2 CHAIRPERSON JANOSKY: Uh-huh.

3 MR. LARSON: Would it not be appropriate to use
4 the wording that's used in the grid minus the word
5 interpretation?

6 CHAIRPERSON JANOSKY: The mandibular rest position
7 and that part on down?

8 MR. LARSON: Yeah, all of those.

9 CHAIRPERSON JANOSKY: Yes, that gets it much more
10 specific.

11 So Question 5?

12 MS. SHULMAN: Everything on the grid except for--

13 DR. RUNNER: Can I just ask one question? For the
14 people that are using these instruments, does identification
15 or recording of jaw movements capture the identification of
16 freeway space and the specific wording that was on the grid?
17 It does not.

18 CHAIRPERSON JANOSKY: Excuse me, Dr. Runner. We
19 had just said that we would change that to be this wording
20 on the grid.

21 DR. RUNNER: I'm sorry.

22 CHAIRPERSON JANOSKY: That was a suggestion by Mr.
23 Larson and we agreed.

24 So it would be then for Question 4, the response
25 would be to identify and record, and then from your text

1 down off of your grid, freeway space all of the way down to
2 interpretation.

3 We are not including--we are still on the one
4 where we are just looking at identification and recording.
5 We are not talking about interpretation.

6 DR. BURTON: Clarification. Are we including the
7 portion beyond interpretation, where it says, "Diagnosis and
8 treatment of" as part of that as well?

9 CHAIRPERSON JANOSKY: No, we are not.

10 DR. BURTON: We are not.

11 CHAIRPERSON JANOSKY: We are not.

12 DR. BURTON: So it's just down to the point above
13 that.

14 CHAIRPERSON JANOSKY: Right. Exactly. So you
15 start at the beginning and you stop at that third comma. So
16 where it says, "to base of skull," that's where the period
17 would go.

18 MR. LARSON: Originally, I thought we were
19 including--we were just dropping the word interpretation or
20 changing the word interpretation to recording. We aren't
21 indicating the purpose for which it's being done?

22 CHAIRPERSON JANOSKY: The purpose being for jaw
23 movements in diagnosis?

24 MR. LARSON: No, in diagnosis and treatment of TMD
25 orofacial pain.

1 CHAIRPERSON JANOSKY: Right. Exactly. I thought
2 we have had that up there. If we didn't, that's my mistake.
3 Yes, we are including that.

4 MR. LARSON: Oh, okay. You just said we were
5 stopping before that.

6 CHAIRPERSON JANOSKY: Let's go through this.
7 Identify and record, and then we say freeway space, identify
8 mandibular rest position, record relationship of the
9 mandible to base of skull. Now the proposal is to place a
10 period here or are we continuing saying of jaw movements in
11 diagnosis and treatment?

12 DR. MOSES: I thought it was just jaw movement.

13 MR. LARSON: And record.

14 CHAIRPERSON JANOSKY: And record jaw movements,
15 period.

16 DR. MOSES: Yes.

17 CHAIRPERSON JANOSKY: Is that the correct--I hear
18 a lot of discussion, but it's not audible enough. Is that
19 essentially--

20 DR. RUNNER: I do have a question. It appears to
21 me that in the device's labeling, as I recall, they do
22 mention TMD in the device labeling. So if we had this
23 indication for use, would this preclude them from mentioning
24 TMD in any of their labeling?

25 MR. LARSON: That's why I was asking that we

1 specifically say, include everything except the word
2 "interpretation." Change the word "interpretation" to
3 "record" or "and recording of jaw movements" and leave in
4 "diagnosis and treatment of TMD orofacial pain" I think
5 would take care of the concerns that would have placed this
6 into class II and yet be definitive.

7 DR. REKOW: I don't have any trouble with all of
8 the answers that we've had so far for diagnosis. I have
9 trouble with some of the answers when we talk about
10 treatment.

11 DR. BURTON: And I would like to echo that as
12 well. That's where I would make the break between those two
13 because, the thing is, I am not sure you have to put TMD and
14 orofacial pain because if it's being used strictly as a
15 recording device, those first statements right there are
16 what it records. And then, again, the practitioner then
17 becomes responsible for the utilization, and interpretation,
18 and applicability to the specific patient.

19 You are assigning it to TMD and orofacial pain,
20 but in reality this could be used for a number of other
21 potential uses.

22 DR. MOSES: But our understanding is that if
23 that's all they wanted, they wouldn't even need to come to
24 the FDA. It's only because they have claims that involves
25 that they had to come to the FDA. And so if we neglect

1 that--it's not true?

2 DR. GUTMAN: I don't believe so.

3 DR. MOSES: They're making--wait a second. DR.

4 RUNNER: It is a medical device, whether it made TMD claims
5 or not. It would still, like, for example, the pantograph
6 is a device that has come through the system and had a
7 classification recommended.

8 DR. ALPERT: So I think the point of confusion is
9 the one that we talked about yesterday a little bit, and
10 that is that, in looking across all of the products, we have
11 identified some that are already classified because they
12 have broad use in other areas, and you can make claims
13 within a broad area. You can make very specific claims for
14 use in neurology, for use in urology, and so forth, within a
15 more global claim.

16 What we have said about these devices is they
17 don't exist in any classification. So it's not a matter of
18 whether they make an overt TMD or not make an overt TMD
19 claim that brought them to the table. What brought them to
20 the table is they are being used, and they are not
21 classified and, therefore, could not fit under any existent
22 classification. That is why we are at the table today.

23 The issue of whether or not you believe they ought
24 to make a claim of TMD is on the table. That's appropriate
25 for you to discuss. That's important, and you might want to

1 make a distinction between a general claim of measuring and
2 trying to make a diagnosis or making more stronger claims
3 about the diagnosis of TMD if that were to be claimed.

4 But what brought us to the table is the fact that
5 these devices are in commercial distribution and have not
6 been classified at all, not at all, not whether or not they
7 make the TMD claim.

8 DR. MOSES: Well, on the one hand, I say to myself
9 that we do use this in crown and bridge, we do use this in
10 prosthodontics, we do need the FDA approval for what I'm
11 hearing. On the other hand, if I put my other hat on and I
12 say, well, now I'm filing an insurance form for approval and
13 if it's not for TMD, they are liable to not pay the claim.
14 So I'm just thinking out loud that maybe that TMD ought to
15 be included.

16 DR. BURTON: I'm not sure that we're in the
17 position to interpret then what we then are assigning to
18 this device and the data that it gives us, giving credence
19 to the fact that it should be a valid measurement device for
20 TMD and orofacial pain. I don't think that's what I have
21 heard the companies claiming. They keep claiming it's a
22 recording device, and we're saying, yes, that's a recording
23 device. The practitioner then is making the decision on how
24 that information is being utilized. If we put that phrase
25 in, then we are saying that this is a device for this

1 purpose, and we are giving--then expanding into the area I
2 think all of us are uncomfortable with saying that this then
3 gives you a parameter for making a therapeutic decision.

4 DR. ALPERT: I believe, Dr. Burton, you are
5 absolutely right. The question is, is it safe and effective
6 to do this or is it safe and effective to make the claim of
7 diagnosis of, and I think those are the claim structures
8 that we are talking about. I believe what I have heard you
9 say is safe and effective for this. That's what I am
10 hearing you say.

11 CHAIRPERSON JANOSKY: Additional discussion?

12 DR. BERTRAND: So in our first vote we were just
13 talking about freeways or record and identify without any
14 implication of TMD. That wasn't clear to me initially.

15 MR. LARSON: Without that, though, wouldn't it
16 have been unnecessary for us to do this, and would it not
17 have been a goniometer by the definition that we see to the
18 left?

19 DR. RUNNER: We considered it significantly
20 different, that it should be classified by itself.

21 MR. LARSON: Technically, aside from its TMD
22 usage?

23 DR. RUNNER: Correct.

24 MS. SHULMAN: Should we read the intended use one
25 more time to make sure there's agreement?

1 CHAIRPERSON JANOSKY: Right. As Dr. Shire has it
2 recorded up there, if we start from that point.

3 MS. SHULMAN: Intended use would be identify and
4 record freeway space, mandibular rest position, record
5 relationship of the mandible to the base of the skull and
6 record jaw movements.

7 CHAIRPERSON JANOSKY: Can I see a show of hands as
8 to the comprehensiveness, as in, yes, this is how you would
9 want the indication for use stated on the supplemental data
10 sheet, a show of hands for those that are in agreement.

11 [Show of hands.]

12 CHAIRPERSON JANOSKY: Six. Dr. Heffez?

13 DR. HEFFEZ: Seven.

14 CHAIRPERSON JANOSKY: Seven. So the majority says
15 this is how it will be listed as indications for use.

16 MS. SCOTT: I have a procedural question that
17 maybe Dr. Gutman or Dr. Runner or someone else can answer.
18 For those devices that are on the market that do have an
19 indication or claim regarding TMD, would the Panel need to
20 recommend another classification for that particular
21 indication, since we have seen it in the labeling in the
22 past?

23 DR. ALPERT: Again, I think we are dealing with a
24 distinction between the device making a specific claim of
25 providing a diagnosis or being useful in patients with X, Y,

1 and Z. And what Pam was just pointing out is that the way
2 the claims have been written in the currently marketed
3 products is with a list of I believe it's five different
4 groups of patients in whom these devices may be used, the
5 ones that you've just talked about, that there are uses in a
6 lot of different patient populations, and the way the claims
7 have been currently structured it says it provides this, and
8 these can be used in these kinds of patients. That I think
9 is what Pam was just pointing out; that it doesn't say just
10 this. It says in patients with TMD and patients with
11 certain kinds of reconstruction, there's a list of the types
12 of patients in whom this instrumentation can be used. It
13 doesn't say it diagnoses those conditions. It says it can
14 be used in evaluation of those patients--patients of all
15 those different types that you were just speaking to.

16 DR. MOSES: So that if they then advertised that
17 this might be useful in the diagnosis of TMD and orofacial
18 pain, they are not going to close up shop as being--

19 DR. ALPERT: That is what was just being pointed
20 out. Pam just pointed out that this then went on to state
21 the types of patients in whom the devices had been used,
22 appropriately, and we can bring those to the table. Is it
23 part of the diagnosis and management of as opposed to
24 providing diagnosis of, and that's where we have been
25 playing this game on semantics all through the process; the

1 question of specifically stating it made a diagnosis versus
2 saying it provides information that is used or can be used
3 in the diagnosis. That is where we got into the statement.

4

5 We can bring the specific statements from the
6 labeling to the table so you can see what they are. Would
7 that be useful?

8 MR. LARSON: I think the question, though, is, if
9 we leave that out, if we leave out both of those, are the
10 manufacturers left out?

11 DR. ALPERT: The issue of intended use and then
12 indications, it's helpful if here--remember, what you are
13 writing here on this form is information that we can use to
14 create a classification and specify what can and can't be
15 done. This is not the entire labeling of the device. This
16 is not the entire labeling of the device.

17 But it would be appropriate on this sheet to help
18 us by looking at the claims that can be made and saying
19 these are the kinds of patients in whom this--or they are
20 not the kinds of patients in whom this technology can be
21 used. That is a claim that has been made for these devices.
22 These are useful in the diagnosis and management of, and
23 then a list of diseases and conditions.

24 DR. BURTON: Without prescribing those statements
25 with those groups, the device could still be classified,

1 would be available for sale and could be utilized by the
2 practitioner for that without being outside of any
3 guidelines.

4 DR. ALPERT: It provides context, if you will, for
5 the manufacturers in structuring their claims. It would be
6 useful to us, again, on the supplemental data sheet to frame
7 it and then we'll figure out how much of that needs to be in
8 the actual classification language.

9 DR. TALLEY: Could we then have the clarification
10 of those items that you just alluded to?

11 DR. ALPERT: Uh-huh. Does one of you have the
12 labeling? We are going to send up for that, so that we can
13 read you the specific claims being made by 510(k)
14 submitters, unless one of the manufacturers has their
15 labeling with them that we could specifically look at.

16 [Pause.]

17 DR. ALPERT: The pre-amendments claims have
18 included use in the diagnosis and management of TMJ MPD
19 disorders, diagnosis and management of orthodontic patients,
20 denture patients, and reconstruction patients, identifying
21 the kinds of patients in whom this can be used in diagnosis
22 or management. Again, TMJ MPD disorders, orthodontic
23 patients, denture patients, reconstruction patients. Those
24 are pre-amendments claims for these devices.

25 Essentially, then it would say, "Identify and

1 record freeway space, mandibular rest position, record the
2 relationship of the mandible to the base of the skull, and
3 record jaw movement in patients with--" it would be the list
4 of the categories of types of patients in whom this has been
5 used legally in the pre-amendments' environment.

6 DR. MOSES: So really when it says, "in diagnosis
7 and management," what you are really saying is providing
8 information which may be used in the diagnosis and treatment
9 or management of the following four conditions.

10 DR. ALPERT: Right. I think you have determined
11 that these devices don't treat.

12 DR. MOSES: No, but they are utilized as aids in
13 the treatment as measuring tools.

14 DR. ALPERT: That's what management means to us.

15 DR. MOSES: Okay. The word management is okay.

16 DR. ALPERT: You don't want to give them a
17 treatment claim, unless you are sure that they are safe,
18 effective, and provide treatment.

19 DR. MOSES: Fine. Fine.

20 DR. ALPERT: Management is the way we use it. We
21 have to worry about what all of the words mean. Is that
22 helpful?

23 CHAIRPERSON JANOSKY: Is this agreed upon, that
24 additional phraseology to Question 4?

25 DR. REKOW: That phraseology is only adding those

1 patient lists, not diagnosis and management, right?

2 DR. TALLEY: Just in patients with.

3 DR. REKOW: In patients with TMJ, blah, blah,
4 blah.

5 CHAIRPERSON JANOSKY: So diagnoses and management
6 is not there.

7 DR. MOSES: I thought it said providing
8 information to use the diagnosis and management.

9 DR. BURTON: I think that that is what the terms
10 above that are information. I'm not sure you have to
11 restate it.

12 DR. MOSES: Well, by saying providing information,
13 it differentiates from making a diagnosis.

14 DR. ALPERT: If I may, one of the things that we
15 are not asking is to write the specific claim that each
16 manufacturer will make. They actually modify the wording
17 all of the time, and we can have five 510(k)s within the
18 same category for the same intended use under the same
19 classification and have five different statements of
20 intended use. As long as they are appropriately included in
21 this wording, then we don't try to write the claim for the
22 manufacturer. They tell us what they are going to claim and
23 we tell them if it fits or not. That is their prerogative
24 as to exactly how they word it, and we're not trying to
25 stick the words to them today. The idea here is to

1 categorize, to understand what the products are that we are
2 actually including.

3 DR. MOSES: I understand what you are saying. My
4 only point is that if the Panel is reluctant to say for
5 diagnosis and management, that it's information which may be
6 used in the diagnosis differentiates it from a freestanding
7 diagnostic tool, those words.

8 DR. ALPERT: And I think what you just said is
9 what's trying to be captured; the fact that it's--

10 DR. MOSES: Providing information useful.

11 DR. ALPERT: Again, this is a supplemental sheet
12 to just fill out and give context and texture to the
13 classification and guide us in what you believe these
14 devices actually have been established for in this
15 classification. So that wording is very helpful here.

16 [Simultaneous discussion.]

17 DR. MOSES: No. It may be used in diagnosis and
18 management.

19 DR. ALPERT: In diagnosis and management of--
20 right.

21 DR. MOSES: We've left out providing information
22 again.

23 DR. ALPERT: We are writing an overarching
24 category of product as opposed to the specific claim of each
25 product.

1 CHAIRPERSON JANOSKY: I was just going to ask for
2 a reading of--

3 DR. SHIRE: The way the indications for use
4 currently read, the way they currently read: Identify and
5 record freeway space, mandibular rest position, record the
6 relationship of the mandible to the base of the skull, and
7 record jaw movements in the diagnosis and management of TMJ,
8 orthodontic, denture, and reconstruction patients.

9 DR. TALLEY: Could I offer, perhaps, a little
10 verbiage to maybe clean this up somewhat. Could you put
11 that back up, though, for me, so I could refer to what I am
12 cleaning up. Thank you.

13 The management of TMD/orofacial pain,
14 orthodontics, and prosthodontics, and that could be fixed
15 and removable prosthodontics might be best--fixed and
16 removable. That way we eliminate the word "patient" and
17 "dentures" and "reconstruction" and vague terminology.

18 Thank you.

19 DR. SHIRE: The management of TMD/orofacial pain,
20 orthodontics, and fixed and removable prosthodontics.

21 DR. ALPERT: And there will be variations on it
22 because people will say in management of patients with and
23 such.

24 DR. BERTRAND: There seems to be a little bit of
25 confusion between management and treatment of TMD, as I hear

1 people discussing this around here. I'm not sure I
2 understand the difference between management and treatment.
3 To me, they are fairly synonymous.

4 DR. ALPERT: Right. But what we are
5 distinguishing is that these devices are not making a claim
6 to provide the treatment. That's the distinction we are
7 trying to make here because we use very few words in these
8 things. If we say they treat, then that means they are
9 providing the treatment as they are used--management means
10 being part of how you evaluate patients. That's what we
11 were trying to convey. It's been very difficult for us, but
12 we are trying to distinguish between those devices that
13 actually impact, from a treatment end, the patient; an
14 implant, a device delivering energy that is treating. That
15 is what we were trying to distinguish, which is why we said
16 management.

17 DR. REKOW: So then this also suggests that it
18 doesn't treat to a threshold; for instance, it doesn't treat
19 to a particular path. It's only that it gives you
20 information that you are or are not there, but it's not a
21 direction that you are necessarily going.

22 DR. ALPERT: That is correct. The issue here is
23 that for many devices that we regulate, the effectiveness is
24 clearly impacted and the usefulness is clearly impacted by
25 the practitioner, and it's very difficult for us to, or for

1 the manufacturer, for that point, to exactly say how--put
2 the limits around the use.

3 Let me go to the meat of the issue. No, this is
4 not setting people up that if you don't use this then you
5 would be considering not managing the patients properly.

6 DR. REKOW: Nor does it also say, hopefully, that
7 if you accomplish something within a certain threshold you
8 have an effective device.

9 DR. ALPERT: Again, these devices--the ones we are
10 talking about right now--are measuring, as opposed to
11 answering, and that's the question. That's where you are
12 going, I believe, from my understanding of what you said.
13 It's the same device now with the next claim is where I
14 think you are going.

15 DR. REKOW: Right.

16 CHAIRPERSON JANOSKY: So moving on to Question 5?

17 DR. REKOW: Yes.

18 CHAIRPERSON JANOSKY: Dr. Shire, can you re-read 4
19 for the record.

20 DR. SHIRE: Indications for use: Identify and
21 record freeway space, mandibular rest position, record the
22 relationship of the mandible to the base of the skull, and
23 record jaw movement in diagnosis and management of
24 TMD/orofacial pain, orthodontics, and fixed and removable
25 prosthodontics.

1 CHAIRPERSON JANOSKY: Shall we move on to 5?
2 Identification of any risks to health presented by
3 device.

4 DR. MOSES: Suggesting none, based on the lack of
5 adverse reaction reports.

6 CHAIRPERSON JANOSKY: Any comments?

7 [No response.]

8 CHAIRPERSON JANOSKY: Moving on to 6: Recommended
9 advisory panel classification and priority.

10 MS. SHULMAN: Okay. The priority will only apply
11 to class II and class III devices, so we can skip that. And
12 the Panel is Dental, the classification is class I.

13 Question 7. We had already determined that the
14 device is not an implant--correct?--from the first one,
15 life-sustaining or life-supporting. So we can skip Question
16 7.

17 Question 8: Summary of information, including
18 clinical experience or judgment, upon which classification
19 recommendation is based.

20 CHAIRPERSON JANOSKY: Is it reasonable to say the
21 proceedings of the Advisory Committee meeting?

22 MS. SHULMAN: I believe so.

23 DR. MOSES: Background literature--we had books
24 presented to us.

25 MS. SHULMAN: Yes, and the published literature.

1 Question 9, we can refer to 11(a) of the general
2 device questionnaire. That was the restrictions. Refer to
3 Question 11(a) of the general device questionnaire.

4 And the last page of this one. Question 10: If
5 the device is in class I, recommend whether FDA should
6 exempt it from.

7 This is exempt it from. I guess we'll just do one
8 at a time.

9 Registration and listing. Do we have any
10 exemption from registration and listing?

11 The registration and listing is where you would
12 register your device manufacturing plant and list the
13 devices that are being made there.

14 Premarket notification, 510(k).

15 DR. MOSES: Suggest yes. Suggest that it not be
16 required.

17 DR. BURTON: Disagree.

18 DR. HEFFEZ: I can't hear very well, and it's not
19 because they're not speaking--

20 MS. SCOTT: We can all hear you.

21 Remember to speak up, so that Dr. Heffez can hear
22 what's going on.

23 CHAIRPERSON JANOSKY: There was some discussion
24 about premarket notification.

25 DR. ALPERT: I would like to read to you what the

1 statute says are the bases for retaining a class I device
2 under 510(k). This is what is new. So I am going to read
3 you what Congress said.

4 This was their intent: "A report under subsection
5 510(k) is not required for a device intended for human use
6 that is exempted from the requirements of this section under
7 (m)," which refers us to other places, "or is within a type
8 that has been classified into class I under section 513."
9 That is what you are doing. "The exception established in
10 the preceding sentence does not apply to any class I device
11 that is intended for a use which is of substantial
12 importance in preventing impairment of human health or to
13 any class I device that presents a potential unreasonable
14 risk of illness or injury."

15 We are back to those words that I talked about
16 before. So, again, is this of significant importance in
17 preventing impairment of health? Does it provide an
18 unreasonable risk? You have to take that as the thing and
19 its use and figure out whether it meets these criteria and
20 can be retained. You can give us advice. We'll have to
21 make the final determination, but we are looking to you for
22 advice on whether it meets those criteria. The form doesn't
23 say that because, as I said, the form was written before the
24 law.

25 So, again, if you think that the use is important

1 and impairment--that there is a risk here for impairment of
2 health. You can say we need 510(k) or if you think that the
3 risk is unreasonable you can require 510(k). That's the
4 threshold. The threshold is much higher than it used to be.
5 This is a higher threshold than we used to have for
6 exempting devices from 510(k). We may only keep ones that
7 reach a very high threshold, otherwise they are not 510(k).

8 DR. TALLEY: Dr. Albert, if we check then the
9 premarket notification, does that mean that the existing two
10 manufacturers and their products must go back through
11 510(k)s?

12 DR. ALPERT: No.

13 DR. TALLEY: Does this indicate, though, that if
14 this is checked, that a future manufacturer would have to do
15 that?

16 DR. ALPERT: If we can retain them, if you
17 recommend that they be retained in 510(k), that they not be
18 exempt, and the criteria on which you recommend that to us
19 meet the statutory threshold, then these manufacturers, if
20 they significantly modify their devices, would need a new
21 510(k), of which there are now four flavors for just
22 addressing the modification, and any new manufacturer coming
23 in or a new product coming into the market with these claims
24 would need a 510(k)-- if, in fact, we meet the threshold for
25 retention. Otherwise they are automatically exempt.

1 DR. RUNNER: Dr. Janosky, Mr. Jankelson wanted to
2 know if he could address the panel with a comment.

3 CHAIRPERSON JANOSKY: Yes.

4 MR. ROLAND JANKELSON: My name is Roland Jankelson
5 with Myotronics. I would want the Panel to know that at no
6 point have we ever suggested or believed that the regulation
7 that we have existed under to this point, which is
8 essentially the 510(k), as well as good manufacturing
9 practices, should be diminished, and I would think it would
10 be inappropriate that it would be.

11 So my feeling is, when I look at the four
12 categories; registration, premarket notification, records
13 and reports, good manufacturing practice, that those are all
14 current regulation processes that we are under, and I would
15 not expect that they be diminished in any way.

16 Questions?

17 [No response.]

18 MR. ROLAND JANKELSON: Thank you.

19 MR. LARSON: Don't we have some difficulty,
20 though, with that statutory definition of what would retain
21 it as a 510(k) and our answer back on the classification
22 questionnaire to Question 2, which would have led us to a
23 class II designation?

24 DR. RUNNER: You still could have answered yes and
25 retained class I.

1 MR. LARSON: We could have?

2 DR. RUNNER: Yes.

3 CHAIRPERSON JANOSKY: So if we return back to
4 premarket notification and whether FDA should exempt it
5 from, any more discussions about that issue?

6 [No response.]

7 CHAIRPERSON JANOSKY: Can I see a show of hands of
8 those saying no, that they do not want to exempt it from
9 premarket notification.

10 [Show of hands.]

11 CHAIRPERSON JANOSKY: One, two, three, four,
12 five--Dr. Heffez?

13 DR. HEFFEZ: Six.

14 CHAIRPERSON JANOSKY: Six. So we are not going to
15 exempt it from premarket notification.

16 What about (c), records and reports--the same, not
17 exempting?

18 [No response.]

19 CHAIRPERSON JANOSKY: And then good manufacturing
20 practice--the same, not exempting.

21 [No response.]

22 CHAIRPERSON JANOSKY: Continuing on to Question

23 11.

24 MS. SHULMAN: Existing standards applicable to the
25 device, device subassemblies, components, or device

1 materials, parts and accessories.

2 If there is none known, there is none known.

3 [No response.]

4 MS. SHULMAN: Okay. None. We have successfully
5 completed one form.

6 CHAIRPERSON JANOSKY: So at this time I ask if
7 there are any comments from the public before we take the
8 vote. Are there any comments from the public?

9 [No response.]

10 CHAIRPERSON JANOSKY: No. I see no comments.
11 We need a motion, please.

12 DR. REKOW: I move that the kinesiograph, with its
13 purpose to identify and record jaw motion, freeway space,
14 mandibular rest position, the relationship of the mandible
15 to the base of the skull for patients with TMD/orofacial
16 pain, orthodontics, and fixed and removable prosthodontics
17 be approved as a class I device.

18 DR. BURTON: Second.

19 CHAIRPERSON JANOSKY: We have a motion on the
20 floor, and it has been seconded. Is there any discussion?

21 [No response.]

22 CHAIRPERSON JANOSKY: No discussion. Show of
23 hands for a vote.

24 [Show of hands.]

25 DR. MOSES: That was my yes vote.

1 CHAIRPERSON JANOSKY: That is your yes vote. Can
2 I get a poll of the Panel, voting members. If we could just
3 start from the left side, please. Please state your name
4 first.

5 DR. BURTON: Burton, yes.

6 DR. MOSES: Moses, yes.

7 DR. GONZALES: Gilbert Gonzales, yes.

8 DR. TALLEY: Bob Talley, yes.

9 DR. BERTRAND: Peter Bertrand, yes.

10 DR. REKOW: Diane Rekow, yes.

11 CHAIRPERSON JANOSKY: Heffez?

12 DR. HEFFEZ: Yes. Leslie Heffez, yes.

13 CHAIRPERSON JANOSKY: It's unanimous. It carries.
14 Do we need to state a reason for voting?

15 MS. SCOTT: No.

16 CHAIRPERSON JANOSKY: That's comprehensive enough.
17 So we are completed with the first.

18 At this time we will take a lunch break. We are
19 going to reduce that to only 30 minutes. So if we were to
20 return back here at 12:35, and we will continue.

21 [Whereupon, the proceedings were adjourned at
22 12:09 p.m., to reconvene at 12:45 p.m. the same day.]

23 - - -

1 A F T E R N O O N S E S S I O N

2 12:46 p.m.

3 CHAIRPERSON JANOSKY: Does everyone have an
4 additional copy of both of those forms?

5 We had taken jaw tracking and sonography and are
6 treating those separately. We were dealing with jaw
7 tracking, if I remember correctly, and we had talked about
8 recording and identifying the two tasks for that, and now we
9 are moving into recording, identifying, and interpreting.

10 Am I correct in that's the direction that we are
11 going?

12 DR. TALLEY: Yes, ma'am.

13 CHAIRPERSON JANOSKY: So if we work through our
14 general device classification questionnaire, again, the
15 generic type of device is the same as it was before.

16 DR. MOSES: Are we interpreting?

17 CHAIRPERSON JANOSKY: I think that's the new--is
18 that the new claim that we are talking about? If I
19 remember from before, the first--Dr. Shire, do you have that
20 overhead that you had written for us before? We could take
21 a look at that again just to make sure my memory is correct.

22 We had identified and record, and we have already
23 done that. We classified those devices. Now we have
24 interpretation.

25 DR. MOSES: I would like to speak to that. Being

1 on the grid, I don't know that the Kinesiograph, the
2 Myotronics equipment, does that. So I don't want to do
3 anything that's---

4 DR. RUNNER: But there are devices that have come
5 to us through the 510(k) process with that claim, and as Dr.
6 Alpert mentioned before, if you wish to, you can give a
7 classification recommendation for this potential claim in
8 the future because it would give us some direction as to
9 where we should go.

10 If at this point you don't give any recommendation
11 on that particular claim and we receive such a claim on
12 another device, it would be automatically class III.

13 We already have the claim that has been presented
14 to us in previous 510(k)s. There are other manufacturers
15 besides Myotronics.

16 DR. MOSES: But you would say that by all
17 research--you can't say that. I see. All right. I
18 understand.

19 CHAIRPERSON JANOSKY: Dr. Runner, the issue is
20 that you do have some devices that are making that claim?

21 DR. RUNNER: That have attempted to make that
22 claim. As I recall, we have not cleared that claim, but we
23 have seen that claim in 510(k)s submitted to us, and I think
24 it would be helpful to FDA if the panel would make some
25 recommendations to us as to how we should handle that claim

1 for these devices. Because as I said, absent from a
2 recommendation, it would automatically be a class III claim.

3 CHAIRPERSON JANOSKY: So I say we go forward then.

4 So we are back to Question 1.

5 MS. SHULMAN: Question 1: Is the device life-
6 sustaining or life-supporting?

7 DR. MOSES: No.

8 MS. SHULMAN: Were there any yeses?

9 DR. MOSES: No.

10 MS. SHULMAN: No. 2: Is the device for a use
11 which is of substantial importance in preventing impairment
12 of human health?

13 DR. MOSES: No.

14 MS. SHULMAN: Any yeses?

15 [No response.]

16 CHAIRPERSON JANOSKY: There are some comments?

17 DR. BERTRAND: I still have a hard time saying no
18 to this, but I think the majority is going to go with the
19 no, so I can go with a no on this.

20 MS. SHULMAN: As we said before, you are certainly
21 free to mark it on your sheet if you have anything that you
22 wanted to say.

23 No. 3: Does the device present a potential
24 unreasonable risk of illness or injury? Is that a no?

25 DR. MOSES: No.

1 MS. SHULMAN: Any yeses?

2 [No response.]

3 MS. SHULMAN: No. 4: Did you answer yes to any of
4 the above three questions? No.

5 Go to No. 5. No. 5: Is there sufficient
6 information to determine that general controls are
7 sufficient to provide reasonable assurance of safety and
8 effectiveness?

9 DR. MOSES: No.

10 CHAIRPERSON JANOSKY: I hear a response that says
11 no to Question 5.

12 DR. MOSES: Question 5, I am suggesting though,
13 because we know nothing about its effectiveness, and so I
14 think, in terms of safety, we may say that it's safe, but in
15 terms of effectiveness, I think we need special controls.

16 CHAIRPERSON JANOSKY: Are there any disagreements
17 about responding to no for Question 5?

18 [No response.]

19 CHAIRPERSON JANOSKY: For Question 5 the response
20 is no then. Question 6?

21 MS. SHULMAN: Is there sufficient information to
22 establish special controls to provide reasonable assurance
23 of safety and effectiveness? And I have the overhead of
24 special controls.

25 CHAIRPERSON JANOSKY: If you could show us those

1 again, please.

2 MS. SHULMAN: Can everyone see them? Performance
3 standards, voluntary standards, postmarket surveillance,
4 user information check list, patient registries, guidelines,
5 guidance documents, patient information and education, and
6 subject to 510(k), and there is also other you can put in
7 there.

8 DR. RUNNER: In addition to that, you could also
9 require clinical data that would be part of the 510(k).

10 DR. MOSES: On that one, my suggestion would be
11 performance standards--

12 MS. SHULMAN: I'm sorry to interrupt you. We are
13 just answering that question is there enough, and then we'll
14 go to No. 7 and discuss which ones they are. Sorry.

15 DR. BURTON: For Question 6, then, I recommend no.
16 I'm sorry. It would be yes, and we can go on to 7.

17 CHAIRPERSON JANOSKY: So Question 6 we would
18 respond yes, which is saying there is sufficient information
19 to establish special controls to provide reasonable
20 assurance of safety and effectiveness. Do I hear--I see a
21 head nodding, so--

22 DR. MOSES: I would question, if we don't know
23 what the device is, how do we know what the information is
24 that's proving its effectiveness? We don't have any
25 information. How is that enough information?

1 DR. RUNNER: Well, the device would be the same
2 device, except with the added claim that it could interpret-
3 -

4 DR. MOSES: And I'm asking how we have any
5 evidence of the safety or the reliability--effectiveness of
6 the interpretation without having it in front of us to
7 evaluate?

8 DR. RUNNER: Well, you are saying what kind of
9 data would you need to determine effectiveness. That is
10 what you would be asking now in your special control, what
11 kind of data would you suspect that you might need to
12 establish that claim.

13 DR. MOSES: Then we are on to Question 7, in
14 effect. Okay. I see.

15 CHAIRPERSON JANOSKY: So the response to Question
16 6 is yes.

17 DR. MOSES: I'm sorry.

18 CHAIRPERSON JANOSKY: So we are on to Question 7
19 then.

20 MS. SHULMAN: Question 7: Is there sufficient
21 information to establish special controls to provide
22 reasonable assurance of safety and effectiveness? If yes,
23 check the special controls needed to provide such reasonable
24 assurance for class II.

25 And just as a matter of clarification, the

1 performance standards listed here are the performance
2 standards recognized by rulemaking, and it is not the same
3 as guidance or guideline. If you are talking guidance or
4 guideline, you can go under other or testing guideline.

5 We can go down these one-by-one or you can just
6 open it up.

7 Postmarket surveillance?

8 DR. BURTON: Could you give us a definition of
9 what they really mean in this particular case by postmarket
10 surveillance?

11 DR. ALPERT: The question, I believe, was on
12 postmarket surveillance. We have the authority to require
13 companies to conduct studies for marketed products. And
14 postmarket surveillance can be an aggressive monitoring, if
15 you will, of the first 100 patients--that's a very common
16 thing--or a study, a more standard-type study of the use of
17 the product if there is a concern about, for example, a
18 specific risk. Although you believe it's reasonably safe
19 and effective, but you are concerned that the products may
20 pose a specific risk, you may ask that a study be done to
21 assess that risk in order to quantify the percentage of
22 patients who face that risk or the severity of the injury,
23 if you will, those kinds of things.

24 It's an ability to monitor more closely the actual
25 use of the product, even though it is marketed. Generally,

1 we use, and we have, again, new statute that specify the
2 kinds of products that can trigger a requirement for
3 postmarket surveillance.

4 So although we may want to require it here, there
5 are also thresholds that are in the process of being
6 developed that have to do with the kinds of risks that
7 support the agency, FDA's ability to require a company to
8 continue to study a product, although it is allowed to
9 legally market it.

10 So it's a way of evaluating more real-world use,
11 if you will, but looking for specific types of risk. They
12 are called 522 studies in the statute and those are the
13 kinds of criteria. It's what's the risk, is it significant,
14 and is that the most appropriate way to go after it.

15 So that's what postmarket surveillance is, and
16 it's in balance if you have a threshold amount of
17 information premarket, but need--longer term, for example,
18 we can do out to 36 months with certain devices. For
19 example, they were an implant and we had a year of implant
20 information was sufficient to make a marketing authorization
21 because the surrogate markers at a year are quite predictive
22 of safety and effectiveness, but durability, you might want
23 to know more about durability at two years or three years.
24 We can require a company to continue a study of patients at
25 least 36 more months and then it's renewable if it's

1 necessary to know that. And let's say for an implant we
2 don't know what the real lifetime of the implant or whether
3 there's a problem at two or three years, don't want to hold
4 it from going to market, but want to be sure that we capture
5 that kind of information on each and every product, we can
6 do that in postmarket surveillance studies.

7 DR. RUNNER: For example, in the dental area, TMJ
8 implants required postmarket surveillance and any implant
9 that goes to market through the 510(k) process before the
10 PMAs are called for have a required postmarket study.

11 DR. ALPERT: You may want to come back to that one
12 after you discuss others because it depends whether you then
13 determine that if they need premarket clinicals, that may
14 obviate anything you might want postmarket. The order is
15 not important. It's a matter that these are up for
16 consideration.

17 DR. GONZALES: In order to interpret jaw movements
18 in the diagnosis and treatment of TMD, in the situation
19 where the data doesn't exist, we are going to need to, it
20 seems to me, make recommendations so that that data then
21 exists. Now postmarket surveillance, the studies, the 522s
22 that was mentioned is one method of doing it. If we look
23 down at the other methods of this special controls, it seems
24 to me that postmarket surveillance of all of the choices
25 here, just without knowing anything else about them, about

1 these others that we have available would seem to be the
2 best.

3 DR. ALPERT: You can ask for clinical studies and
4 have it be in the 510(k).

5 DR. GONZALES: In fact, I thought that's what that
6 was is the clinical studies.

7 DR. ALPERT: No, you can ask for premarket
8 studies. That's postmarket. That's saying they go to
9 market, and then they do some additional work. You could
10 ask for, as was pointed out--put up the list again--you
11 could ask for clinical studies, either a full study or a
12 clinical experience in a certain number of patients
13 premarket. It's something that you may ask for under--it's
14 not on that list, but special controls includes being able
15 to say that clinical trials, a clinical trial, clinical data
16 are necessary to establish those thresholds.

17 There are lots of things that can be considered as
18 special controls, and if you look on this list, you will see
19 that animal studies or clinical studies can, in fact, be
20 specified as a control for products in class II.

21 So you can say there's enough to know that it's
22 reasonably safe and effective, but in order for a company to
23 label with a specific threshold and a specific claim, they
24 need to do a clinical study that establishes it or you can
25 say that they need animal studies to show that--it depends

1 on the product. There are many products where the animal
2 studies answer the question and others you need clinicals.
3 But there's lots of--and you see training shows up there as
4 well.

5 DR. GONZALES: Can a postmarket surveillance that
6 shows that the device is, in fact, not, in other words, a
7 negative study, could that lead FDA to reclassify or remove
8 the classification because it has now been shown to be
9 ineffective? Do you need a clinical study before the device
10 goes out to do that or can that same kind of control be
11 obtained with a postmarket surveillance?

12 DR. ALPERT: They are quite different, and let me
13 take your questions one at a time.

14 The first question you asked is if, in fact, there
15 is a postmarket study that demonstrates that there is
16 ineffectiveness or what we call unreasonable risk for a
17 patient population, can the agency take action? Yes, but
18 generally the response to that is to do some labeling
19 changes and require more information because, on the basis
20 of one single study, we wouldn't necessarily pull all of the
21 devices off the market. That would be inappropriate.

22 The real question that you are getting to is the
23 one of what is the amount of information, since the first
24 question that you have answered is there is valid scientific
25 evidence that says this is safe and effective for this use

1 or it is safe and effective and people want to make a claim
2 for this use.

3 You can determine that there is enough
4 information, enough preliminary information to say it can be
5 in class II, but each device needs to establish its
6 threshold in a premarket trial and in premarket testing,
7 whatever the appropriate testing is.

8 What you are implying is that there is a concern
9 that safety and effectiveness for an absolute diagnostic
10 claim may not be established, and you always have the option
11 to put that claim in class III, requiring that it be
12 established in PMA. The difference is the claim is okay,
13 and we understand that, in fact, this is reasonably safe and
14 effective, but we don't know what the right threshold for
15 every device is. We can't set a threshold for diagnosis.
16 We can't say every single jaw-tracking device has the same
17 criteria for diseased versus nondiseased patients. We know
18 it can do it, but we don't know what that threshold is for
19 each device, so each device needs to establish it by itself.
20 That's a special control in class II.

21 Or you may say the whole concept has not been
22 established as being effective, and that would put it in
23 class III. That's one of the questions that you are being
24 asked. That is the question of whether it is safe and
25 effective and then where is the right category.

1 So putting it in class II means you have made some
2 threshold determination, and now you are saying each device
3 may need to do these things, each company needs to do these
4 things in order to make this claim.

5 Is that helpful?

6 DR. GONZALES: Yes.

7 DR. GUTMAN: Let me just add a comment, which is
8 that the postmarket studies are usually viewed--usually,
9 again, and anything is possible--usually need to be somewhat
10 supplementary to the premarket; that you wouldn't usually
11 think of establishing safe and effectiveness only through
12 postmarket study. You would use that to perhaps decrease
13 the threshold of premarket data requirements and then
14 perhaps refine information, change labeling, get more
15 insight into it as a result of the postmarketing, but we
16 wouldn't normally think of the postmarketing as a single
17 path towards actually establishing safety and effectiveness.
18 That would be an unusual way to go about it.

19 DR. GONZALES: But how much data do we have? And
20 since we are addressing interpretation, how much data do we
21 really have right now that we know it helps in
22 interpretation?

23 DR. GUTMAN: You actually need to maybe revisit
24 the previous question because the issue is do you have
25 enough data to be comfortable with special controls and if,

1 in fact, the background is sufficiently unclear to you, then
2 maybe you don't have enough data to establish special
3 controls, and maybe this really deserves to be a class III.
4 I mean, that's again, I don't know, but I hope you do or you
5 can at least advise us.

6 DR. GONZALES: I am not familiar enough with the
7 literature regarding interpretation. I'm much more
8 dependent upon the dental people here to help with that.
9 But from what I have heard, it seems to me that there is a
10 question about taking it to that level of inter--using this
11 for interpretation. If that's the case, if there is not
12 enough information, then maybe clinical studies should be
13 done before it is used for interpretation. That's the first
14 thing.

15 And, Dr. Alpert, you mentioned something about
16 never going back or rarely going back or it's unusual to go
17 back and then restrict the device. But isn't that what
18 actually happened with silicone implants; that it was--

19 DR. ALPERT: Actually, silicone implants were
20 preamendments devices that were placed into preamendments
21 class III. The Agency was directed by a Panel that, in
22 fact, safety and effectiveness had not been established
23 adequately. They were not pulled from the market at the
24 time that a Panel determined they were preamendments, but
25 needed to be in class III. Class III meant that eventually

1 the FDA needed to call for PMAs.

2 They did that, but the Classification Panels made
3 that determination in 150 products, approximately, asking
4 the FDA to establish a schedule for calling for PMAs for
5 devices where they felt, in most cases, not there was undue
6 risk, you ought to pull them off the market, but where the
7 safety and effectiveness, even though they were already
8 marketed prior to May of '76, there wasn't enough
9 information to really understand that they were safe and
10 effective.

11 The Agency then put together about four years ago
12 a list and a pattern schedule for calling for PMAs. The
13 issue there is that these claims were being made, the
14 products were being marketed, the claim needed really
15 establishment, something that we rarely get into. But that
16 is what happens for preamendments products that are
17 considered class III, generally because they are already
18 being marketed for these uses.

19 If a preamendments device is placed into class
20 III, there is a time and process that is invoked. We will
21 take a hypothetical. Hypothetically, we say this is class
22 III, this claim is class III. The Agency is then directed
23 to call for PMAs, but we are also directed not to call for
24 them, not to even put out the notification that we will be
25 calling for them. We have to notify people they are in

1 class III and that we will call for them. They get a
2 minimum of 30 months to prepare the information. In those
3 30 months, they may market those through 510(k) for that
4 claim.

5 At that point in time, when we call for them, they
6 have three months to give us the information. If a company
7 marketing a preamendments III device that has been called
8 for does not file a PMA, then they have to go out of the
9 market or go under investigational device exemption. But
10 there is a time period provided for the manufacturers to
11 develop safety and effectiveness information to support a
12 PMA, but we're not allowed to call for 30 months.

13 That is, again, for those products where the
14 concern is that their safety and effectiveness has not been
15 established and these kinds of controls will not be
16 adequate. You need a full PMA, soup-to-nuts, in the
17 establishment of safety and effectiveness. This is
18 predicated on the idea that we understand enough about the
19 safety and effectiveness of those products to put them in
20 the category, even if we would like individual manufacturers
21 to provide clinical data. It's the difference between the
22 category and the individual device.

23 DR. MOSES: At this moment, I put on my consumer
24 hat, and I say let's assume I have a jaw-tracking device,
25 and they come up with new software, and I say to myself,

1 unless they tell me that it's experimental, and they're
2 telling me that it's not, I think it's unfair to sell the
3 thing without that kind of premarket approval.

4 But what I am hearing you say is they can do that
5 under that for 30 months.

6 DR. ALPERT: Under 510(k).

7 DR. MOSES: Under 510(k), which means--

8 DR. ALPERT: It means they have to come in for a
9 premarket clearance. It means they have to provide data to
10 us, and we have to say, yes, you may market this device for
11 this use based on the data you have provided us.

12 DR. MOSES: That sounds more reasonable. What is
13 that one called, again?

14 DR. ALPERT: That's--

15 DR. MOSES: That's premarket approval.

16 DR. ALPERT: Premarket notification, 510(k). 95-
17 plus percent of devices reaching the market in the U.S. go
18 through the 510(k) process. It's an abbreviated submission.
19 They are not required to establish individually from, again,
20 from soup to nuts with every bit of design and testing the
21 safety and effectiveness of the product. It's a bit stepped
22 back. It's assuming that the product is reasonable and safe
23 to market, but they need to demonstrate for that particular
24 product how they are appropriate for being like the ones
25 that were already in the marketplace.

1 DR. MOSES: So the question would be on this form,
2 under Item ,7 what will we check if we wanted the 510(k)--
3 other?

4 DR. ALPERT: In class II, the question of
5 exemption is quite different than the one that we just
6 talked--you are going to get to do that on the supplemental
7 form.

8 The question that we are asking here is assume the
9 following: Assume that you have determined that there is
10 reasonable safety and effectiveness to categorize the claim,
11 that there is enough overarching information, generally, to
12 say that these can safely and effectively provide a
13 diagnosis, but that you want each individual manufacturer to
14 provide the information that tells you that their threshold
15 is, in fact, appropriate for that particular product,
16 assuming that they will be slightly different because, as
17 you say, the software, the technology in each of the
18 products is a little different.

19 You might say, okay, we need guidance as to what
20 information ought to come in, in a premarket submission.
21 That special control is guidance, and you might say we'll
22 leave it up to the FDA engineers to figure out what kinds of
23 issues they are. Those guidance documents go out, not for
24 notice and comment rulemaking, but guidance documents go out
25 for comment. So the industry would get a chance to comment

1 on the guidance we were providing.

2 You might say that there needed to be very
3 specific types of bench testing, and that might go in a
4 guidance document. You might say we would like to see
5 animal studies that establish, probably--and, again, this is
6 hypothetical--animal studies that establish that, in fact,
7 this is not going to injure anybody. So you might say
8 animal studies. So we put a special control in place that
9 says there needs to be a 30-month animal trial for
10 carcinogenicity, hypothetical.

11 You might say that every user must be trained and
12 there has to be a training program established by the
13 company to teach practitioners how to safely and effectively
14 use this product. That's a special control. We might say
15 every label has to have these three limitations on their
16 labeling. That would be a labeling control.

17 You might say these special controls, and maybe we
18 want 20 patients, 20 affected and 20 not affected, or maybe
19 we want a one-year study of patients. We do that with some
20 of our implants that are under 510(k) to say they need to
21 bring in six months or a year on 20 patients to show us
22 that, in fact, there are no early failures. That would not
23 be predicted in the other work.

24 But that's based on the fact that you say
25 overarching, not for each individual product going to

1 market, but overarching products of this type for this claim
2 are reasonably safe and effective, and it's reasonably safe
3 and effective, not absolutes. It's reasonable safety and
4 effectiveness for that claim. If you can't get there, then
5 they are in class III, and that's okay. But it's whether
6 you can get there or not.

7 DR. TALLEY: I believe we understand then that if
8 we answer no, that we automatically go to class III for this
9 particular use of this device. If we answer yes and pick
10 out a selected number of these guidelines up here,
11 hypothetically, postmarket surveillance, clinical studies
12 and labeling, how would that impact the manufacturer at this
13 point?

14 DR. ALPERT: The ones that are already in the
15 market, not at all. If they change their device and want it
16 to come in again, we have to go forward and publish a rule,
17 publish a proposal to classify, which we haven't done yet,
18 then have a final classification regulation. Nothing
19 happens to them until we do that.

20 At the time that we then have a final
21 classification regulation in class II with these special
22 controls, any manufacturer putting into the marketplace a
23 significantly modified product or a brand new product, new
24 manufacturer or brand new product, would have to address
25 each of those special controls. They would have to follow

1 the guidance. They would have to set up and have in place a
2 plan for a postmarket surveillance, and on, and on before we
3 could clear their 510(k).

4 CHAIRPERSON JANOSKY: Based upon that discussion,
5 let's revisit Question 7 at the top. Is there sufficient
6 information to establish special controls to provide
7 reasonable assurance of safety and effectiveness, yes or no?

8 DR. BURTON: Yes.

9 CHAIRPERSON JANOSKY: Do I hear--we are on the
10 main decision point of Question 7. Is the response yes or
11 no?

12 DR. HEFFEZ: Is this for diagnostic tests?

13 CHAIRPERSON JANOSKY: We are talking about
14 identification, recording, and interpretation. The answer
15 is yes?

16 DR. MOSES: My suggestion is it is a no.

17 CHAIRPERSON JANOSKY: No. Okay. I thought I
18 heard one response of yes and one response of no.

19 DR. MOSES: I will share my thinking with you, is
20 I have this anxiety: For example, hypothetically, in my
21 mind, I could think of software, for example, that might
22 analyze a chewing stroke using a kinesiograph. So the
23 question I want to ask is, is that interpretation that it's
24 going to give, based on the chewing stroke, going to be
25 effective? It's not just a statistical analysis that I'm

1 going to look at saying, Oh, there's so many people, but I
2 want corroborative data probably based on open-joint surgery
3 to validate what it is. In other words, how do I know what
4 they are saying is really true unless there is substantial
5 corroborative data in a situation like that, which is quite
6 a simple thing.

7 In any case, I can't think of what I want, and so
8 I have to say no because just because they use this device
9 doesn't mean it's going to be a totally benign analysis that
10 they use or that it won't be--just because they are using a
11 jaw-tracking device doesn't mean the software, or whatever
12 the interpretative device is going to be, is going to be
13 effective.

14 And I don't know what research would be
15 appropriate to validate it. You can't answer that question.
16 That's a hypothetical device, and you don't even know what
17 the device is. So I don't see how you could answer that
18 question, short of knowing that device.

19 CHAIRPERSON JANOSKY: So you are arguing no for
20 the prior response of 7.

21 DR. MOSES: That's my argument.

22 CHAIRPERSON JANOSKY: Can we do a poll of hands
23 for Question No. 7?

24 DR. BURTON: I said yes, and the reason is I
25 think, at least what I saw presented in terms of what we

1 could request, in terms of clinical trials and performance
2 standards, would allow I think if the guidelines would be
3 written in such a way that it would allow us to evaluate
4 that safely. I think, again, we are going back to what the
5 device is, and I think if we require, make it subject to
6 510(k) with clinical trials would give us sufficient data to
7 allow it to come in as a class II and allow it to be studied
8 sufficiently to see whether it meets those standards or not.

9 So I guess I take the opposing view. I would say,
10 yes, that I think we could establish those special controls
11 to make it a class II.

12 CHAIRPERSON JANOSKY: So I hear one argument for
13 yes and one for no. Any more discussion before we just take
14 a poll of hands?

15 [No response.]

16 CHAIRPERSON JANOSKY: So, again, Question 7, can I
17 please see by a show of hands how many respond yes, responds
18 yes to Question 7.

19 [Show of hands.]

20 CHAIRPERSON JANOSKY: Two to the response of yes.

21 I take it then all of the others would choose no
22 as the response to 7.

23 [Show of hands.]

24 CHAIRPERSON JANOSKY: So response of 7 is no.

25 DR. HEFFEZ: Yeah.

1 CHAIRPERSON JANOSKY: So, if no, classify in class
2 III.

3 Ms. Shulman, where do we go from this point? Do
4 we go down to Question 8?

5 MS. SHULMAN: Questions 8 and 9 only apply for a
6 performance standard. So that does not apply, so we can
7 skip 8 and 9. We would go to No. 10, and that is: For a
8 device recommended for classification into class III,
9 identify the priority for requiring premarket approval
10 applications. And that is what Dr. Alpert was speaking
11 about and the priority is high, medium, or low or N/A, if
12 that's appropriate.

13 DR. MOSES: Dr. Alpert, does the high, low, or
14 medium priority affect the amount of time they get to do the
15 study?

16 DR. ALPERT: Yes, it does. It directs us, because
17 we have to consider workload as well, it tell us that, if
18 it's high priority, it's saying tell them now that they have
19 30 months. Medium priority might say it's not a rush, and
20 low priority would say when you get to it, essentially, to
21 signal we're going to call for PMAs, but we're not going to
22 call for them for five years.

23 Realize that this, again, was written when we were
24 doing 150 or more devices, and the idea was to sort them.
25 If you had a lot of class IIIs, how do you sort them in

1 terms of being able to schedule, sorting them by how high a
2 risk is it to allow them to continue to market under the
3 current parameters?

4 DR. MOSES: So, if I understand it then, what you
5 are saying is they can have as long as they want to do the
6 research, but it's how fast you get to evaluate the research
7 is the priority we give it.

8 DR. ALPERT: The call. Now we're in a kind of
9 unusual situation here. What class III here means is we
10 would look to see is there a--I don't know that there is a
11 preamendments claim. Susan is saying no. Susan Runner is
12 saying no. The issue is, is there a preamendments class III
13 claim for these devices, and I think the answer--

14 DR. RUNNER: I'm not entirely sure, but we have
15 not allowed that claim in the labeling at this point.

16 DR. ALPERT: That would mean that right now there
17 is no currently marketed product making that claim.
18 Therefore, any product wanting to make that claim could only
19 go to market under PMA. We don't have to call for them
20 because there are no currently marketed products,
21 preamendments that were marketed prior to May 28, 1976, in
22 this specific area with this specific claim.

23 It simply says anybody who wants to make this
24 needs a PMA. They can come in whenever they've got the
25 data. We don't have to call. We don't have to do anything.

1 The companies come to us when they are ready.

2 DR. MOSES: So then I'm correct that priority is
3 your priority in doing it?

4 DR. ALPERT: No. The priority almost doesn't
5 apply. It applies of the claim were already on devices
6 marketed prior to May 28, 1976.

7 DR. MOSES: Thank you.

8 DR. ALPERT: Again, what we have been trying to do
9 is give you the global and then apply it to the specific,
10 and it gets a little tricky. It's important for us because
11 what you are saying is safety and effectiveness for this has
12 not been established. Therefore, anybody who wants to make
13 this claim needs a PMA. That's what you are saying.

14 And because they weren't already making the claim,
15 they can't be in the marketplace now absent a PMA. That's
16 what this means. No one is making that claim now. No one
17 who has got that information, that we know of, made the
18 claim. Prior to '76, that's what they would have had to do
19 to be in the marketplace with that claim. Today, we are
20 unaware of anyone.

21 One last comment. Again, this is all--we have
22 determined that there was nobody marketing with that claim.
23 So it's not preamendments. A company, one of the current
24 companies or somebody new, wanting to make that claim needs
25 a PMA.

1 Their alternative is to look and identify a
2 product that was, in fact, marketed before the law came into
3 effect, with that claim, and establish preamendment status.

4
5 We have numerous companies who have found things
6 that were marketed that we couldn't find. Once they find
7 them, if they find a product that was in the marketplace
8 with that claim, really being commercialized for that claim,
9 they may then come in with a 510(k). What your decision
10 here will help us, if someone does that, is to say, Okay,
11 it's preamendments. It's a III. We need to call for PMAs.
12 It's very helpful to have this signal.

13 But a company could find a product having that
14 claim and, as I said, we have had several companies who have
15 identified preamendments claims, including in this area,
16 that we were unaware of.

17 DR. MOSES: Again, relative to this, I feel that,
18 while we don't want to be prohibitive of new devices coming
19 out, I want to know, if I am going to use it, is it
20 effective and it's, again, I feel like we're doing a
21 different thing here, other than devices that are around 21
22 years, you are asking me the device may have been around 21
23 years, but you are saying to me how much--do you want
24 premarket testing on this thing to assure efficacy? Because
25 I presume that if it's software, it will be safe. That

1 doesn't seem to me to be a prohibitive factor in bringing it
2 to market.

3 DR. ALPERT: We approve anywhere between 30 and 60
4 PMAs a year. We don't think it's prohibitive either. We
5 also have a new process called a product development
6 protocol, which impacts, and Heather Rosencrantz from the
7 510(k) staff is here to correct something I am saying I am
8 sure.

9 Let me say that's not prohibitive. If you
10 determine that these are not classifiable, then what's
11 essentially being said is any company wanting to come
12 forward with that claim needs a PMA. The PMA, if it's an
13 established company, may contain only the clinical trial,
14 and that may be the only piece that's missing is the
15 establishment. We are not talking about your using it. We
16 are talking about the company being able to market and
17 promote with the interpretation their label.

18 DR. MOSES: So that if the company comes to you
19 and says, with this product development protocol, we want to
20 develop this, they can certainly find the doctors to help
21 them to test it, for whom it would be--

22 DR. ALPERT: They can do their research.

23 DR. MOSES: Okay.

24 DR. ALPERT: We don't stop the research. It's a
25 matter of marketing authorization.

1 DR. MOSES: Okay. Fine. Thank you.

2 DR. TALLEY: Madam Chairman, with respect to No.
3 10, it would be my suggestion then that we classify this as
4 a high priority.

5 CHAIRPERSON JANOSKY: Agreement?

6 DR. GONZALES: Wouldn't we mark off not
7 applicable, since there are no devices that are in the works
8 right now? There's no point in putting a priority if there
9 are no devices.

10 CHAIRPERSON JANOSKY: Dr. Alpert, can we please
11 have--

12 MR. LARSON: Dr. Alpert has suggested that it
13 would be helpful to them if we do give them an indication,
14 in case somebody comes up with a preamendments device.

15 DR. ALPERT: And that's what Ms. Rosencrantz was
16 just commenting on as well; that it's not a formal
17 classification. It's basically saying we've classified
18 these claims into class I, which is what you did earlier
19 today, and everything else, essentially, is in class III.
20 We brought this one up because it was a point of discussion,
21 and the question is, is this an established claim; is this
22 something already being claimed formally or informally? Is
23 it an established issue, and what do you think about it?
24 Because we get challenged on those issues all the time.

25 And you have made a distinction between this kind

1 of claim and the other claim that you have said is class I.
2 So you don't have to go any further here. You can say,
3 Okay, we've made that distinction. Only the thing that we
4 classified this morning is a legally marketed claim for
5 these devices. Everything else is a PMA. And you don't
6 need to go any further working on this, and you can actually
7 move to the other device.

8 MS. SHULMAN: Is everyone in agreement with that?

9 DR. TALLEY: Yes.

10 DR. MOSES: Yes.

11 CHAIRPERSON JANOSKY: Do we need a motion? Can I
12 have a motion, please?

13 DR. TALLEY: Yes. I would make a motion that the
14 kinesiograph classified to identify, record, and interpret
15 be classified as a class III instrument or device.

16 DR. MOSES: Second.

17 CHAIRPERSON JANOSKY: We have a motion on the
18 floor, and it has been seconded. Is there any discussion?

19 [No response.]

20 CHAIRPERSON JANOSKY: We'll poll the Panel,
21 starting with voting members.

22 DR. MOSES: Moses, yes.

23 DR. BURTON: Burton, yes.

24 DR. GONZALES: Gilbert Gonzales, yes.

25 DR. TALLEY: Talley, yes.

1 DR. BERTRAND: Bertrand, yes.

2 DR. REKOW: Rekow, yes.

3 CHAIRPERSON JANOSKY: Heffez?

4 DR. HEFFEZ: Heffez, yes.

5 CHAIRPERSON JANOSKY: The motion carries.

6 We are moving on. Going through the general
7 device classification questionnaire, once again. This is
8 for the sonography.

9 DR. MOSES: Do we have another blank form?

10 CHAIRPERSON JANOSKY: Can we have some additional
11 forms?

12 [Pause.]

13 CHAIRPERSON JANOSKY: While these forms are being
14 passed out, if we look at the grid again. If TMD-specific
15 intended uses and legally marketed devices, there is a
16 description there also. So the generic type of device,
17 sonography.

18 Now the question becomes do we consider it as one
19 device or do you want to look at the issue of the device and
20 its use, like we had done before?

21 DR. MOSES: Suggest using the device as one and
22 the interpretative device as two.

23 CHAIRPERSON JANOSKY: So the suggestion is to
24 break them up again. That is describing--let me back up.
25 What did we use before?

1 DR. MOSES: Data acquisition.

2 CHAIRPERSON JANOSKY: Identifying and recording as
3 one, and then the other would be sonography for identifying,
4 recording, and interpreting. That is a suggestion. So we
5 would handle this device in a similar manner to which we had
6 handled the previous device. Do we hear any disagreement/

7 DR. ALPERT: And in order to avoid what we just
8 did, I guess, the first question is one of the questions to
9 ask right at this point is, is there a preamendments claim
10 for--what is the currently marketed claim for these devices?
11 Let's do that because I think that will help. What's
12 currently on the labels?

13 DR. RUNNER: The currently marketed claim does not
14 include interpretation.

15 DR. ALPERT: Do we know what the words for that
16 claim are?

17 CHAIRPERSON JANOSKY: So the devices on the market
18 only have claims--

19 DR. RUNNER: I have that right now. For one
20 product, "Is a noninvasive device that measures and records
21 sounds emitted from the temporomandibular joint along with
22 assessing the status."

23 Excuse me. "Is a noninvasive device that measures
24 and records sounds emitted from the temporomandibular joint
25 along with the relative position of the jaw as a means of

1 assessing the status of the temporomandibular joint."

2 DR. TALLEY: Dr. Runner, my understanding and the
3 Panel's understanding from previous discussion, that another
4 manufacturer does represent that their device interprets?

5 DR. RUNNER: We have seen that claim. However,
6 that has not been cleared by the Agency. That was brought
7 up just as a claim that we have seen in 510(k)s, but we have
8 not cleared that claim. So we would like your input as to
9 the status of that claim, but we have not cleared the claim
10 for interpretation of jaw sounds.

11 DR. SHIRE: Please repeat.

12 DR. RUNNER: Is a noninvasive device that measures
13 and records sounds emitted from the temporomandibular joint.
14 I believe I was continuing on with the combination device
15 that is a jaw-tracking device. It measures and records
16 sounds emitted from the temporomandibular joint.

17 CHAIRPERSON JANOSKY: So the claims are measuring
18 and recording. There are currently no devices that are
19 claiming to interpret.

20 DR. RUNNER: Correct.

21 CHAIRPERSON JANOSKY: With that, then, Question 1:
22 Is the device life-sustaining or life-supporting?

23 DR. RUNNER: May I make one clarification? If a
24 device is presently claiming that they are interpreting
25 sounds, they are doing so out of the bounds of the

1 regulatory process, and that will be handled with the
2 regulatory process.

3 DR. GONZALES: Actually, can I just add two cents
4 here about we have been asked to clarify what we mean by
5 interpret, and it would be appropriate, actually, to discuss
6 that.

7 Again, in the diagnostic setting, we probably are
8 talking about actually converting a signal into some kind of
9 diagnostic message, either clinical or diagnostic
10 sensitivity or clinical diagnostic specificity; that, in
11 general, when we look at laboratory tests, I don't know so
12 much here about these kinds of diagnostic tests, we are
13 looking for reasonable surrogates of outcome, and we are
14 looking for biologically plausible outcomes. We don't
15 usually require long-term outcome studies to demonstrate
16 that the information will unequivocally do a particular
17 thing.

18 Now you may wish to take either a more liberal or
19 a more conservative stance, but we are looking for, when we
20 talk about interpreting, we are looking for ways to take
21 information and make it clinically meaningful.

22 CHAIRPERSON JANOSKY: My understanding is we are
23 currently classifying devices that claim to record and not
24 interpret; is that correct?

25 DR. GONZALES: Yes.

1 CHAIRPERSON JANOSKY: Ms. Shulman, should we work
2 through the questionnaire again?

3 MS. SHULMAN: Sure. Question No. 1: Is the
4 device life-sustaining or life-supporting?

5 DR. MOSES: Suggest no.

6 MS. SHULMAN: No. 2: Is the device for a use
7 which is of substantial importance in preventing impairment
8 of human health?

9 DR. BURTON: Suggest no.

10 DR. MOSES: Second no.

11 MS. SHULMAN: No. 3: Does the device present a
12 potential unreasonable risk of illness or injury?

13 DR. MOSES: Suggest no.

14 MS. SHULMAN: No. 4: Did you answer yes to any of
15 the above three questions? No.

16 Go to No. 5: Is there sufficient information to
17 determine that general controls are sufficient to provide
18 reasonable assurance of safety and effectiveness?

19 DR. MOSES: Suggest yes.

20 MS. SHULMAN: Any disagreements?

21 [No response.]

22 MS. SHULMAN: Then there is classified in class I,
23 and we then we can--

24 CHAIRPERSON JANOSKY: Go to Question 11(a).

25 MS. SHULMAN: Go to 11(a).

1 CHAIRPERSON JANOSKY: Correct.

2 DR. BURTON: 11(a), suggest no.

3 MS. SHULMAN: 11(a): Can there otherwise be
4 reasonable assurance of its safety and effectiveness without
5 restrictions on its sale, distribution or use, because of
6 any potentiality for harmful effect or the collateral
7 measures necessary for the device's use? Again, this is a
8 prescription question.

9 DR. BURTON: Second no.

10 MS. SHULMAN: No. Then, if no, go to 11(b):

11 Identify the restrictions. Again, they are the first one:
12 Only upon the written or oral authorization of a
13 practitioner licensed by law to administer or use the
14 device.

15 DR. MOSES: Suggest only the first one be checked.

16 DR. BURTON: Second.

17 MS. SHULMAN: Any disagreements?

18 [No response.]

19 MS. SHULMAN: Then we'll go to the supplemental
20 sheet.

21 No. 1: The generic type of device; sonography for
22 measurement, measuring and recording.

23 Advisory Panel.

24 No. 3: Is the device an implant?

25 DR. MOSES: No.

1 MS. SHULMAN: No.

2 Indications for use prescribed, recommended, or
3 suggested in the device's labeling that were considered by
4 the Advisory Panel.

5 DR. TALLEY: Madam Chairman, could I suggest that
6 on our products to consider for classification by the Dental
7 Products Panel grid that we accept the TMD-specific intended
8 uses for the legally marketed device as presented, with the
9 deletion of the first word "and" and the word "interpret,"
10 leaving the body of other information alone.

11 Would you like for me to read that?

12 CHAIRPERSON JANOSKY: Please.

13 DR. TALLEY: As read then it would state: To
14 classify specific joint sounds in the diagnosis and
15 treatment--oops. I would also like to delete the word
16 "treatment"--of TMD/orofacial pain, to measure and record
17 sounds emitted from the TMJ as a means of assessing TMJ
18 status.

19 Deleting three words then--and, interpret, and
20 treatment.

21 DR. MOSES: Would you consider substituting
22 management there because we do take afters as we go along?

23 DR. TALLEY: I would agree to that since it's
24 consistent with our previous listing.

25 CHAIRPERSON JANOSKY: Okay. Any disagreements?

1 [No response.]

2 CHAIRPERSON JANOSKY: Any discussion?

3 [No response.]

4 CHAIRPERSON JANOSKY: Moving on.

5 MS. SHULMAN: Can we get you to repeat that one
6 more time, so we can write it down, please.

7 DR. TALLEY: Yes. To classify specific joint
8 sounds in the diagnosis and management of TMD/orofacial
9 pain, to measure and record sounds emitted from the TMJ as
10 means of assessing TMJ status.

11 MS. SHULMAN: Thank you.

12 No. 5: Identification of any risks to health
13 presented by the device.

14 DR. MOSES: None.

15 MS. SHULMAN: None.

16 No. 6: Recommended Advisory Panel classification,
17 and that is, again, class II and III only. So the
18 classification is dental class I.

19 No. 7: If the device is an implant, or is life-
20 sustaining or life-supporting and has been classified in a
21 category other than class III, explain fully. But it,
22 correct, is not an implant.

23 No. 8: The summary of the information, including
24 clinical experience or judgment, upon which classification
25 recommendation is based.

1 Again, if you wanted to say the Panel meaning in
2 the literature that was provided before.

3 DR. TALLEY: Agreed.

4 MS. SHULMAN: Question 10: If the device is in
5 class I, recommend whether FDA should exempt it from, again,
6 registration and listing. That's the registration of the
7 manufacturing sites and the listing of the devices;
8 premarket notification, otherwise known as 510(k).

9 DR. TALLEY: Madam Chairman, I suggest no
10 exemptions.

11 DR. MOSES: Second.

12 CHAIRPERSON JANOSKY: No exemptions for 10.

13 MS. SHULMAN: And No. 11: Any existing standards
14 applicable to the device; device subassemblies or device
15 materials that are known.

16 None known?

17 DR. MOSES: Were we discussing design? Before we
18 had basically touched on design controls. Perhaps we could
19 ask for an interpretation from Dr. Alpert for design
20 controls as they might apply here or, if not, so be it.

21 DR. ALPERT: Again, the design controls are a
22 process the manufacturer uses to be sure that their design
23 and testing, as they modify their device, meets--or that the
24 testing, as they develop their device and modify it, meets
25 the objective of their design.

1 So they set up a process as part of their
2 manufacturing that says we are designing this product to
3 have these parameters and they need to continue to meet
4 those parameters and document that they meet those
5 parameters as they modify change and manufacture their
6 product. That's a design control file, and it's a
7 manufacturing process issue. It's not a specific testing
8 issue. The companies determine what those tests are that in
9 their design controls file. They have to be appropriate for
10 what they are intending their device to do, but it's not a
11 clinical intending. It's a performance, bench performance
12 intending.

13 DR. MOSES: Is that applicable as a--

14 DR. ALPERT: The question is one of are these
15 devices of a sufficiently complicated sort that this would
16 be an appropriate control on the manufacturing of the
17 devices; for example, very simple class I devices that have
18 no moving parts and no software. Software devices,
19 generally, as a blanket, class I devices with software are
20 put on the design controls list because the appropriate
21 design and testing of software requires a design controls
22 file.

23 So we have, essentially, determined that any
24 device containing software needs a design controls approach,
25 and we, therefore, list those products in class I as

1 retaining design controls.

2 There are very simple devices in class I that
3 don't need that, where no one believes that the
4 manufacturing is so complicated or the device technology is
5 so complicated that adding that requirement of maintaining
6 that kind of file for inspection adds any additional levels
7 of assurance for the performance of the product, and I mean
8 bench performance.

9 These types of products, where there is software
10 involved, would all almost automatically we would do it. If
11 you had not recommended it, we would normally list these as
12 design controls, as requiring design controls, because of
13 the software. It's the only way to assure that software
14 maintains good design. It's an approach we take.

15 DR. MOSES: I would suggest then that, in this
16 case, it be added.

17 CHAIRPERSON JANOSKY: The suggestion is to add
18 design controls.

19 DR. ALPERT: Again, it's not on the list because
20 it's new. Welcome to the government in transition.

21 DR. GONZALES: If we add design controls that
22 include what we had discussed earlier, the accountability;
23 that is to say--let me make sure I understand right now.
24 The design controls are design controls on the device to
25 make sure it's doing what the claims are stated and not

1 necessarily--

2 DR. ALPERT: Not quite. Design controls are a
3 mechanism that the--essentially, it is a file that the
4 company--

5 Let's say you were starting from scratch. Let me
6 take you back a step. You are going to design a product.
7 When your engineers are sitting down to design a product,
8 they figure out what kinds of testing and outcomes of that
9 testing will be appropriate for different aspects of the
10 design; the bio materials, what kind of a process they need
11 to have in place for developing and changing software,
12 electrical safety kinds of issues. They create a set of
13 criteria that they want the design to meet, and then they
14 build the device and test it against their goal for the
15 product. They maintain that in a file. That's a design
16 controls file.

17 They go back and they change something in the
18 device and retest it. It has to meet their criteria or they
19 have to look at why it didn't and figure out whether it
20 changes the safety and effectiveness of the device. It's a
21 manufacturing and development issue, not a performance in
22 the clinic issue. It's a control on good manufacturing
23 practices as opposed to a control on performance in the
24 clinic. They are connected because you assume that they
25 designed it to do what it's doing.

1 DR. REKOW: For instance, I think as an example
2 from when I was in industry, if we bought something that was
3 to measure the same thing, but we bought it from a different
4 vendor, you have to document all of that, and you have to
5 document the vendor, and then you have to prove that it, in
6 fact, performs the same way. You can't just say the vendor
7 said it's true, so it is true. You have to do all of those
8 tests in-house. So it's that kind of control.

9 DR. ALPERT: Acceptance criteria for components,
10 exactly. That's a good example.

11 DR. GONZALES: So is there an ongoing issue with
12 sonography that would suggest that we should put in
13 accountability regarding this? Has there been something
14 that has come up or an issue that has developed in the
15 development of sonography or the way it's been used that we
16 should even include some form of design controls and
17 accountability?

18 DR. ALPERT: The question, I think, the first
19 question is, is there software in this device, and if there
20 is software in this device, then it's a matter of the kinds
21 of controls we put in place for software development.

22 Again, because design controls is part of new
23 regulatory oversight, the decision having to be made for
24 class I devices is based on the fact that it was thought to
25 be--pardon the expression--overkill for many very simple

1 devices; that putting that requirement on somebody who
2 manufactures very simple devices didn't make sense.

3 But as the device gets a little more complicated,
4 the technology is a little more complicated, it's simply a
5 very good way that manufacturers should have in place to
6 develop their products, and we get a chance to look at it.

7 CHAIRPERSON JANOSKY: So the addition of design
8 controls or not?

9 DR. MOSES: I am suggesting it, and I would vote
10 for it.

11 CHAIRPERSON JANOSKY: So we are completed with
12 this form. Any comments from the public before we call for
13 a motion?

14 [No response.]

15 CHAIRPERSON JANOSKY: Call for a motion.

16 DR. MOSES: So moved.

17 DR. BURTON: You have to move something.

18 DR. MOSES: I move that the supplemental data
19 sheet be approved as written.

20 CHAIRPERSON JANOSKY: For classifying.

21 DR. BURTON: I move that we accept sonography for
22 measurement and record as a class I device with the approval
23 of the supplemental data sheet as well.

24 DR. MOSES: Second.

25 CHAIRPERSON JANOSKY: We have a motion, and it has

1 been seconded. Is there any discussion?

2 [No response.]

3 CHAIRPERSON JANOSKY: Let's poll the Panel,
4 please, starting with the voting members.

5 DR. BURTON: Burton, yes.

6 DR. MOSES: Moses, yes.

7 DR. GONZALES: Gonzales, yes.

8 DR. TALLEY: Talley, yes.

9 DR. BERTRAND: Bertrand, yes.

10 DR. REKOW: Rekow, yes.

11 DR. HEFFEZ: Heffez, yes.

12 CHAIRPERSON JANOSKY: Motion carries.

13 Dr. Runner, am I correct in that we do not need to
14 do sonography for interpretation?

15 DR. RUNNER: Correct.

16 CHAIRPERSON JANOSKY: That is correct. We do not.

17 DR. RUNNER: That is correct.

18 CHAIRPERSON JANOSKY: Are there any other issues
19 that we need to consider. Dr. Alpert?

20 DR. ALPERT: I just want to make sure that
21 everybody understands the impact that the classifications
22 that we have just heard you recommend have on the devices
23 and the labeling, and labeling includes instruction manuals.

24

25 What you have just told us, and I just want to

1 make sure that that's what we heard, before we move out of
2 these two devices, that claims for interpreting that a
3 certain noise is associated with a certain disease state is
4 not included in these classifications, so, therefore, no
5 manual that is supplied with these devices may make a claim
6 that a given noise or pattern is associated with a set
7 disease. I just want to be sure that you are aware that
8 that is, in fact, what these classifications say.

9 MS. SCOTT: I have one other thing that may need
10 to be clarified in addition to what Dr. Alpert said. A
11 given noise or pattern related to a disease state and also a
12 given noise or pattern related to a physiological state.

13 DR. ALPERT: Disease or condition. I tend to say
14 disease, but disease or condition. That is the impact of
15 what was just determined in terms of classifying the claim
16 and not addressing the other claims. I just wanted to be
17 sure.

18 And, again, as in the earlier one, what that is
19 saying is that devices wanting to make claims other than
20 this would have to come in and establish those claims. They
21 can try to do it under this blanket, but they have to
22 establish the claim.

23 DR. BURTON: Dr. Alpert, can I ask just one
24 question? That obviously applies to the sonogram. But to
25 the kinesiograph then you are saying then that they also

1 cannot make a--they can claim that there are various types
2 of movements or changes in movements in terms of management,
3 however, that none of those are also equatable to any
4 specific problem?

5 DR. ALPERT: That is correct. That is what you
6 are directing us. That is why I wanted to sound this with
7 you, to be sure that everyone at the table understood that
8 that was what the impact of this recommendation is. I said
9 that wrong, but that is the impact of this recommendation.

10 DR. TALLEY: Dr. Alpert, therefore, do we need to
11 provide a secondary classification for sonographic
12 instrument that follows the verbiage outlined in our handout
13 or grid?

14 DR. ALPERT: What I understand, and I am going to
15 turn to Dr. Runner, the issue is were there any
16 preamendments devices in sonography that made claims, other
17 than the claim that was just classified?

18 DR. RUNNER: Not that we are aware of.

19 DR. MOSES: There's a question in the back there.

20 CHAIRPERSON JANOSKY: I'm sorry. The gentleman in
21 the back had requested first.

22 Dr. Tilley?

23 DR. TILLEY: I don't want to speak for the
24 manufacturer, but I think it needs to be a point of
25 information that there are some programs that show very

1 significant--statistically significant, rather--readings
2 that indicate specific things. Dr. Bisette has just done
3 one on chewing that has just come out just recently, he and
4 a fellow in Japan, and I don't remember the name.

5 But there are quite a few studies on sonography
6 that show specific patterns relate to specific diseases.
7 And one of his studies shows as high as a 96 percent
8 sensitivity and an 80 percent, I believe it was,
9 specificity, better than any test we have anywhere. So that
10 needs to be made clear that it's available, and the research
11 backs it up. I don't know what their claims are, but it's
12 certainly out there.

13 Thank you.

14 DR. ALPERT: And that speaks to the issue the fact
15 that there are studies, publications available, is quite
16 different from what the manufacturers may claim on the
17 product. What we just classified is what manufacturers may
18 claim for their product.

19 The fact that there is also literature that people
20 can refer to to make their determinations, we expect that.
21 In fact, that was something that Mr. Jankelson spoke to
22 earlier, that one expects practitioners in the field to go
23 to the literature and see how these things are, in fact,
24 being interpreted and used. That is where one goes or to
25 one's mentors or to one's peers or to meetings to find out

1 where the current thinking is about interpretation of lots
2 of things. But the manufacturers may not make those claims
3 in their marketing, promotion, labeling kinds of things.

4 DR. MOSES: Dr. Alpert, I have a question. There
5 are two things I think I heard there. I heard Larry Tilley
6 saying that he is aware of these studies, but I am asking is
7 it also available on your computer? Is it, in fact,
8 available and being sold, to your knowledge?

9 DR. TILLEY: I'm not sure. You would have to ask
10 Bob.

11 DR. ALPERT: The question that was pertinent here
12 was whether or not preamendments there were any products of
13 that sort. If we then became aware that someone was--

14 DR. RUNNER: Everything that we do is
15 confidential, but if we were to become aware of a
16 manufacturer that was making the claim for interpreting
17 sounds, then we would take the appropriate regulatory action
18 because we are not aware of that being a preamendments
19 claim, and we have not cleared that claim in the 510(k)
20 process.

21 DR. ALPERT: And what the impact of what Dr.
22 Runner said is that, legally, no company has been granted
23 authority to market with that claim. Therefore, that claim,
24 if a company wants to make it, needs to come in through the
25 PMA process. They need to get approval to make that claim

1 because it is a new and different claim from the
2 preamendments claims that have been made for these products,
3 and if they were marketing and promoting for them before
4 they had the claim, then there are enforcement actions that
5 might be taken.

6 DR. MOSES: But, in fact, the device to which it
7 was being compared on the grid is a class II apparently did
8 interpret. I mean, when you are talking about a stethoscope
9 here, it did interpret.

10 DR. ALPERT: What's on the grid in already
11 classified classifications were provided as background. The
12 issue on the table is the preamendments claims for these
13 devices. They were provided to tell you what other devices
14 are out there. That's why we provided them on the grid,
15 what happened to other devices that make those claims, but
16 they were established either preamendments or postamendments
17 and classified.

18 DR. MOSES: Thank you.

19 CHAIRPERSON JANOSKY: Mr. Jankelson, you earlier
20 wanted to make a comment.

21 MR. ROLAND JANKELSON: Yes. My name is Roland
22 Jankelson with Myotronics.

23 Two issues: One, I am totally confused as to why
24 a classification was provided for the kinesiograph that
25 interprets when there is no such device on the market and

1 when, in fact--

2 DR. RUNNER: Excuse me, Mr. Jankelson. I think
3 that going through the grid or the questionnaire was a
4 mistake on our part. We did not classify that. They gave
5 us a recommendation.

6 MR. ROLAND JANKELSON: I think this creates a
7 substantial imbalance. There is a product on the market, a
8 sonography product, which makes claims, I understand perhaps
9 not legally, but that makes claims about interpretation.
10 And having gone through a process that arrived at a specific
11 recommendation that differentiated on the kinesiograph that
12 a recording device was a class I--that was the
13 recommendation--but if you go to expansion of the claim to
14 include the ability to interpret, which, to me, through this
15 entire two-day discussion has meant making a claim about
16 being independently diagnostic, that's the second issue I
17 want to cover, because I need clarification with respect to
18 the manufacturer's ability under--pardon the pun--this
19 interpretation as to what the manufacturer can say about
20 what's out there in the literature, what's out there in the
21 research.

22 I mean, we don't operate in a void, in the sense
23 that I've told you that we have two devices that record and
24 display information, but I have not for a moment implied
25 that we don't have a relationship to how that information is

1 absorbed by the clinician who is going to be using the
2 instrumentation in a way that we believe is going to be
3 beneficial. That information and that responsibility is
4 with the clinician.

5 But are we being told that if we make any
6 reference to the state of the science or the state of the
7 art in terms of what is in the literature, what is in the
8 research, what is in the clinical experience, that we are
9 now creating a claim for interpretation? Because if that's
10 the case, that's ridiculous.

11 DR. ALPERT: The law is very clear. The
12 manufacturers wanting to place specific claims on their
13 products are required to provide the appropriate
14 demonstration of safety and effectiveness. The fact that
15 these devices are, in fact, under study or that there is
16 research associated with them that has information that is
17 of use to the clinicians is, of course, no. I mean, we
18 don't work in a void.

19 Our obligation, however, is to be sure, to assure
20 you and the practicing community, that information on the
21 label has been validated and that the claims made by the
22 product are, in fact, valid claims, and we just went through
23 the process of identifying claims for these products that
24 were considered to be established as reasonably safe and
25 effective.

1 And, in fact, they did not say that one could, by
2 using specific cut-offs, differentiate between one category
3 of patient and another. They did not say, and that was why
4 I raised the question. That's exactly why I raised the
5 question before you moved on, to be sure that you recognize
6 that what that means is the manufacturer may not say this
7 pattern is associated with this disease or that patients
8 with this pattern have this disease because that is, in
9 fact, interpreting the sound to be associated with the
10 disease. That was the question that we raised.

11 A manufacturer can bring in research, can bring in
12 those publications, and have that as supporting information
13 to add that claim to their label. That is perfectly within
14 their right and would be appropriate, either research that
15 they, themselves, supported or research that's being done in
16 the community. Both kinds of research are available to them
17 to bring in, in a submission, to say we now want to make
18 this claim.

19 What we classified is the basic claim, not--what I
20 heard was that what you were recommending is that the
21 criteria upon which to differentiate different groups of
22 patients using this information was absent, to your minds,
23 and, therefore, you could not say that a claim for a certain
24 threshold for all of the devices made sense at this point in
25 time; that you couldn't say this pattern or this noise level

1 or this sound is associated with this disease or condition
2 of the patient. That's what I heard you say in terms of the
3 recommendation for a class I kind of general acquisition of
4 information claim for these products.

5 There are lots of other places, Mr. Jankelson, in
6 answer to your question, regarding what a company can do
7 with published studies, and there are many things--if a
8 company is asked by a practitioner, "Well, is there
9 information about how to interpret this?" they may
10 distribute published information. That is allowed. They
11 can't write it in their label, but they can distribute that
12 information in response to a practitioner's request.

13 There is also work being done now under FDAMA that
14 talks about how a company can distribute, as part of their
15 marketing and promotion, published papers. That's been in
16 court recently, and the Agency is being given direction by
17 the courts in terms of what restrictions we may place on
18 companies for the distribution of peer-reviewed published
19 literature, and that's changing. Providing peer-reviewed
20 published literature, either up front or in response to a
21 question, is quite different from what goes on the label.

22 Our job is what goes on the label and into the
23 labeling, the manuals, and the marketing information, the
24 published information that goes with the product, and those
25 are separable to us. So the literature, of course, and the

1 experiences available to you, Mr. Jankelson, to provide to
2 practitioners when asked and, as we move forward it looks
3 like there will also be an opportunity for you to provide
4 them, as long as it's peer-reviewed literature, in other
5 ways and as part of training, but that's not the labeling,
6 and what we're focusing on here is what goes into the
7 labeling.

8 That's not to say, as we listed all of those
9 diseases, that this information is useful in patients with
10 these diseases, that these diseases and conditions are
11 associated with abnormalities of the joint that can, in
12 fact, be assessed using this equipment. It's figuring out
13 which picture, which pattern is associated with a disease
14 that was determined not to have been a preamendments claim,
15 per se, that was thresholded for all of the products. That
16 is what I heard. If that's not where we are, this was a
17 recommendation we can rediscuss.

18 Does that answer your question?

19 MR. ROLAND JANKELSON: No.

20 CHAIRPERSON JANOSKY: Dr. Cooper?

21 DR. COOPER: Thank you. Barry Cooper. I need
22 clarification. I have really been trying very hard to
23 follow this whole complex technical process. There is no
24 device on the market which claims to interpret jaw
25 movements. Yet we went through a lengthy process, shorter

1 than the first, of going through a classification process
2 for a jaw-tracking device with interpretative claims. So
3 there is none on the market, but we just classified it as
4 class III.

5 There is something on the market, but the FDA
6 doesn't officially know about it, that prints out
7 computerized data that says 97 percent certainty of
8 perforated disk and so on and so forth. This is on the
9 market. But the FDA doesn't know about it, but we're not
10 going to classify it. I don't care if you do or don't, but
11 I don't understand why it's done for one instrument and
12 isn't done for the other, when officially there are neither
13 on the market.

14 DR. ALPERT: We determined and, again, I am going
15 to take you back. Mr. Jankelson referred to it and Dr.
16 Cooper referred to it. We said, as Dr. Runner pointed out,
17 that the second process we went through in the jaw-tracking
18 device was not appropriate because this was not a
19 preamendments claim. We did ask for some discussion to see
20 was this an established claim, and we found out it was not
21 an established claim. Therefore, that whole piece of the
22 process we realized after the fact we should not have gone
23 down that road for original classification of a
24 preamendments product, an unclassified preamendments
25 product.

1 If there were products marketed through PMA or
2 that would be in class III, and I know this is going to get
3 even more complicated, if, in fact, we establish that there
4 are products with this claim that should be, by statute, in
5 class III, then a Panel, such as yourselves, can say we
6 think that belongs in class II, but that is a reclass, a
7 down classification procedure. They are very similar. They
8 require the same kinds of information, very much the same
9 discussion that we just had.

10 We recognize, however, we should not have done the
11 second piece of the jaw-tracking. That was an error, and we
12 are not considering that as a formal recommendation of this
13 Panel because we concluded, after that, that it was not a
14 preamendments claim. I just want to make sure everybody
15 heard that. That is as if it never happened because it was
16 inappropriate. We should not have done it, but we didn't
17 recognize that until we got through it. So we are saying
18 that is inappropriate activity that we did at this meeting.
19 We should not have done that because it turns out it wasn't
20 preamendments.

21 MS. SCOTT: Dr. Alpert, could you clarify one
22 other thing?

23 DR. ALPERT: Uh-huh.

24 MS. SCOTT: If a company wants to come in with a
25 postamendments claim, such as interpretation or any other

1 type of claim, do they have the option or can you clarify
2 whether or not they have the option to come in with a 510(k)
3 and demonstrate substantial equivalence based on data.

4 DR. ALPERT: She is actually asking two separate
5 questions, which I am going to get to, but I'm going to let
6 Mr. Jankelson ask me the question on what I just said first
7 and then go on to the other issues.

8 MR. ROLAND JANKELSON: This is a very quick
9 question, and I think you answered it, but I am going to ask
10 you to articulate in even less equivocal terms, and your
11 terms, I think, were actually quite specific.

12 Am I correct in assuming that we have vacated for
13 the record the action in classifying jaw tracking that
14 claims to interpret? So what happened here didn't happen
15 for any official purposes. For purposes of the record, we
16 have classified two devices, neither of which are allowed to
17 make claims regarding interpretation.

18 Now, a statement, I still--

19 DR. ALPERT: Let me say absolutely to both of
20 those. We did two devices, neither one was for the
21 interpretative-type claim that we talked about specifically
22 identifying populations.

23 We also heard you say that there is someone
24 marketing that. We will take that under consideration and
25 refer it to the appropriate folks in our Compliance Office,

1 who investigate and take appropriate action for people
2 marketing beyond what they are appropriately legally allowed
3 to market.

4 MR. ROLAND JANKELSON: I want to leave here
5 feeling that I absolutely know what is appropriate for us to
6 do as a manufacturer in terms of marketing and communicating
7 information to the marketplace that does not cause you or
8 someone from this part of the country to call me and say,
9 "You are doing something that we judge to cross the line to
10 interpretation."

11 I want to ask, in time, as appropriate, to have my
12 brother make some comments about the kinds of things that we
13 would be communicating to the marketplace about the state of
14 the science or the state of the art, which we would deem to
15 be appropriate and consistent with the remarks that we have
16 been consistent about that the Myotronics' two devices are
17 recording devices. They are not independently diagnostic.
18 But I have never said that the company is not associated
19 with certain concepts about why the information has
20 relevance.

21 So you understand why I might be confused and why
22 it is important that I leave here not feeling that I am
23 confused.

24 DR. ALPERT: I think it is a tricky issue, and I
25 don't doubt for a minute that you are not the only person in

1 the room confused.

2 Again, the fact that the kinds of claims that were
3 discussed specifically state this information is useful in
4 diagnosing and managing patients with these diseases or
5 conditions. It did not say that these devices--it didn't
6 say that there is a certain threshold for being able to
7 claim or that there was data available to demonstrate that
8 one could safely and effectively make a distinction between
9 a patient with such a condition and a patient without such a
10 condition that was classified; in other words, had the Panel
11 felt that the data, the literature, the presentations made
12 established that these devices can, in fact, differentiate,
13 then they might have said differentiation is a preamendments
14 claim that is being made now. It's been made.

15 And that was one of the questions. What's the
16 preamendments claim? Preamendments devices did not make
17 that claim, if I understand correctly. There was no
18 interpretation. There were no--what the answer is, and
19 that's what I heard. So that was not being classified.

20 But if you were to market and promote and say,
21 "Patients with this pattern have this disease or condition,"
22 that that is something that you would have to establish with
23 data to us, and it might be class III. That might be a PMA
24 claim. It might require the establishment of safety and
25 effectiveness for that threshold. That's what is being

1 said.

2 In answer to your other question, that does not
3 mean that doctors use these things in a vacuum. We don't
4 expect them to. The state of the art, the medicine moves.
5 But the issue of how you direct them to that information is
6 important in what you may market and promote. And I suggest
7 that, as we move forward--and, again, this is a
8 recommendation. We have not made this determination yet.
9 We will chew on it. We will put it together in a proposal.
10 We will make comments on all of these things in a regulation
11 proposal. You will have an opportunity, again, to comment
12 on it in a proposed regulation.

13 During this period of time, you continue to market
14 your current products and come through 510(k) as you have
15 done. That does not change until--and may not change even
16 when there is, in fact, a regulation in place. But you will
17 have an opportunity to comment on the regulation and on
18 these issues in any proposed regulation. So I want to
19 assure you you have additional opportunities about these
20 finer points about what information is and is not included
21 because we will be very careful to address those issues as
22 we move forward.

23 So right now nothing changes. Right now nothing
24 changes.

25 Pam asked a question because there's an issue.

1 There's an opportunity again for manufacturers. There's an
2 opportunity. We have new rules.

3 A manufacturer may come to us with one of these
4 outcomes claims. You want to put in your marketing and
5 promotion patterns and say, "This means this disease. This
6 means this patient has a captured disk. This means this
7 patient has something else." You come in, in 510(k), and we
8 say, "No, not substantial equivalent." You may come back to
9 us and say, "We think that it's not substantial equivalent
10 because there's no preamendments claim, there's no
11 established claim, but that this is no more risky than
12 what's out there. We have lots of literature showing this.
13 We have lots of experience showing this. We want to be
14 originally classified."

15 We have a new provision, another piece of new law-
16 -and you think it's hard for you, let me tell you, it's very
17 difficult for us as well--we have a new piece of law which
18 says a device that is not substantially equivalent because
19 there is no established claim of this sort can come in and
20 ask for what we call evaluation of original class III. It
21 means, if there is no 510(k) for it, it is by statute in
22 III. The company says, "We want a reevaluation of that. We
23 disagree. We think this is so low-risk and so obviously
24 safe and effective, you ought to give us a classification,
25 and it ought to be the same classification as these other

1 things, but we want our own classification."

2 We evaluate all of the data, all of the paperwork
3 and can make a determination about that evaluation of
4 original class III.

5 Alternatively, given the development of data in
6 the clinical community, a manufacturer may petition us and
7 say, "We've got all of this information. We petition you,
8 FDA, to classify this claim for these already marketed
9 products into the same class as the current ones or even in
10 a lower class." It is another way of moving products into
11 classification and claims into those classifications.

12 What we did today was looked at claims that were
13 in the marketplace prior to the advent of the first medical
14 device amendments in '76 and say, "What's the right category
15 for those claims?" That's what we did today with the two--
16 only two--things that we recommended to be in class I.
17 Those were old claims, products not considered before they
18 needed to be classified.

19 There are options, these other options are
20 available for claims that are new, that are postamendments
21 claims, claims that have been made since the law was put in
22 place, that have originated after the law was in place for
23 these devices. Postamendments claims there's a different
24 process. There's a petition process. There's a down-
25 classification procedure we can initiate or a company can or

1 an interested party can or a special re-evaluation of the
2 original classification.

3 We have a lot of tools that allow us to get to
4 this process, but we only have this tool for the claims that
5 were made prior to '76. This is the only way we can get
6 there from here.

7 I hope that clarified.

8 MS. SCOTT: If I can ask Dr. Janosky to recap
9 briefly what we actually classified and then any
10 postamendments claims are automatically class III and, as
11 Dr. Alpert just explained, the postamendments claims we have
12 a new way that we can handle those postamendments claims.

13 Dr. Jankelson, I believe you had some information
14 regarding specific information that you provide as part of
15 your advertising possibly or as part of your communication
16 to clinicians, and if you could state those briefly, and
17 then if the Panel could comment on whether that specific
18 information falls within that which was classified.

19 So we will let Dr. Janosky review what was
20 classified and then of those specific pieces of information
21 that you provide, the Panel, if you read them quickly, and
22 then the Panel can comment if they fall within the claim or
23 indication that was classified.

24 CHAIRPERSON JANOSKY: We classified two devices;
25 one is for kinesiography and the other one is for

1 sonography, and both of these had the purpose or the use to
2 identify and record. We classified both of those as a class
3 I device.

4 Dr. Jankelson, did you then want to make--DR.
5 ROBERT JANKELSON: Dr. Robert Jankelson with Myotronics
6 NeuroMed, Inc. I do have a financial interest.

7 First of all, I would like to compliment the work
8 of the committee. You have all worked very hard, and I
9 think the questions have been concise and pertinent, and so
10 I am here really to just clarify, so we all, at the end of
11 two long days, feel comfortable because we have already
12 dealt with the problems of semantic obfuscation, and TMD,
13 and occlusion, and so on, and we don't want it to become an
14 issue retrospectively at the end of this Panel.

15 So I am going to make several comments and ask Dr.
16 Gutman or Dr. Alpert whether my interpretation is correct.
17 I would like to thank Dr. Gutman for some I thought very
18 pertinent and concise analogies in his area of expertise in
19 what we are dealing with here.

20 Albert Einstein said the definition of complexity
21 is that which you don't understand, and I thought he made it
22 very simple. So I will try to relate my understanding to
23 what he has said.

24 First of all, interpretation by a device means
25 taking in information, data, and through some form of

1 artificial intelligence, artificial programming, it comes to
2 a conclusion. Is that a clear statement? There has to be
3 some form of artificial intelligence in which the computer
4 makes some determinants and has a--

5 [Laughter.]

6 DR. JANKELSON: I got one yes and one no.

7 DR. ALPERT: Actually, interpretation may be made
8 by the device itself or by the labeling of the device, and
9 that's part of the device.

10 I believe the distinction you are drawing is
11 whether the software prints out a little piece of paper that
12 says 98 percent of the time this is going to be associated
13 with something or whether that is done on a piece of paper
14 in the manual, and there is no distinction to us, if the
15 company is making that claim, whether they are making it
16 based on data analysis within the piece of equipment or they
17 are making that in the manual.

18 The impact is the same; that an interpretation has
19 been made that 98 percent of the time a patient with this
20 pattern has this, and it's not so much whether the
21 electronics tell you that on a fancy machine or whether the
22 manual tells you how to read it. I just want to make sure
23 that that was clear.

24 DR. ROBERT JANKELSON: And I understand that.

25 Going back to a very clear analogy, let me take the most

1 simple condition that I can imagine in dentistry. You have
2 a patient presents and they open 19 millimeters. They have
3 no deviation. For the dentists here, I think we'd come to
4 the conclusion that the patient has a closed lock unilateral
5 because it doesn't deviate. Fair enough? Everybody agree?

6
7 That's your deductive impression because you know
8 the patients that can't open past 19 millimeters and don't
9 deviate can't free the condyles on either side, but you
10 don't know what it is. Is it adhesions, muscle spasm? Is
11 it a mechanical blockage of the disk? The data cannot tell
12 you those last three questions. Is that a fair statement?
13 And that is the differential that you later have to gain
14 from additional information.

15 Am I safe in making this assumption or not?

16 In other words, I am trying to see if we are
17 thinking alike here. Because, again, we have to understand
18 this word "interpretation" and records and displays and how
19 that record and display is utilized, if not by the computer,
20 by the clinician, and I think that's really what is central
21 here.

22 So if I see on my jaw-tracking recording a maximum
23 opening of 19 millimeters, can I say that is a closed lock
24 if I am teaching? I would like a clarification. Because it
25 really gets down to the essence of what myself and a number

1 of us here can teach because we have a database, a
2 literature base, that clearly suggests that when the patient
3 cannot open past 19 millimeters it's a closed lock. But we
4 don't know whether it's reversible, nonreversible.

5 DR. ALPERT: Dr. Jankelson, if I may. Your
6 questions are pertinent, but not for this Panel. The
7 questions that you are asking have to do with--and they are
8 not even appropriate for my office in the sense they are
9 appropriate questions, but not for us. We are not--the
10 determination of when and what can be taught are things, as
11 I said, that are in debate in the courts at the moment. So
12 we are not going to be able to answer them, nor is it this
13 Panel's ability or requirement to answer them.

14 I think your concern that we be very clear about
15 what can be marketed and promoted is an appropriate concern,
16 and you are asking us to be clear, I believe, as we move
17 forward as to what will be considered as within the claim
18 and what will be outside the claim. But we can't--at least
19 I know that I can't, as an Agency person, make that
20 determination for you here because, one, it's not my job
21 alone and, two, because until we have matured the
22 classification and all of the information and had the notice
23 and comment, including your own participation, we don't know
24 where that will wind up. I think those are very appropriate
25 issues, but we can't answer them today.

1 So I would suggest that you identify all of them
2 and make sure that they become part of the record and that
3 they are addressed. But we are not going to be able to
4 address them. The Panel's responsibility, very honestly,
5 the Panel's responsibility is not to determine whether the
6 marketing and promotion that you currently have in place or
7 want to put in place is appropriate. They have been asked
8 to do a classification of preamendments. All I am pointing
9 out is it's appropriate for you to have these on the record,
10 but it's not appropriate to challenge this Panel on them
11 because that's not their--they're not empowered to answer.

12 DR. ROBERT JANKELSON: And I'm asking for
13 clarification because there are a number of doctors in this
14 room, besides myself--I'll be teaching tomorrow what is--

15 DR. ALPERT: As I said, there is no impact of
16 today's action on anything that is currently going on. That
17 follows current rules. Their recommendation from the Panel
18 to the Agency the only impact is for us as we go forward to
19 consider that. It has no impact on the current process at
20 all, no impact, and that was something that was unclear the
21 last time and, really, we do have to differentiate between
22 the work of this Panel and the rest of the work.

23 They did the preamendments classification. The
24 issues that you are bringing up about training, and
25 marketing, and promotion are not issues that this Panel is

1 appropriately empaneled to address. So what I am saying is
2 they can't answer these questions. They are not questions
3 for them.

4 Your question regarding what can be said and can't
5 be said, and labeling, and marketing, and promotion are
6 questions that need to be directed to us after we have made
7 a classification determination. Currently, you have cleared
8 510(k)s and you may market and promote and do what you are
9 legally already authorized to do. No one is going to change
10 any of that, and I don't believe this will change any of
11 that.

12 But, again, marketing and promotion is not on the
13 table or training for this Panel.

14 DR. ROBERT JANKELSON: Just to clarify. I would
15 like to thank you for your time, and attention, and efforts.
16 I asked this for clarification because, again, we don't want
17 semantic issues coming up later that could impact, even
18 though the best intent of the classification could be
19 obscured by some of these later issues.

20 So, again, thank you for your time and effort in
21 this Panel.

22 MR. ROLAND JANKELSON: Roland Jankelson with
23 Myotronics.

24 I did not mean to use the Panel and the Panel's
25 time. I'd like to go home, too, and I know we all want to

1 do that. What started this conversation, Dr. Alpert, was
2 there were some explanations by staff about the definition
3 of interpretation, which became very important because, as
4 the discussion evolved here, it was clear that the Panel
5 recognized the difference between a more benign device that
6 recorded and displayed and a device that purported to make
7 independently diagnostic interpretations at some significant
8 level.

9 So the word "interpretation" really became very
10 operative here and leaving this Panel with a class I
11 classification is obviously, considering where we have been
12 four or five years ago, is great progress from our point of
13 view.

14 But we understand, in fact, I think we raised the
15 issue, that if claims are made about the ability of a
16 technological device to independently diagnose or to provide
17 information which by itself is claimed to be independently
18 diagnostic, that device is something very different than
19 what we have represented our device to be.

20 And so as the explanation of interpretation that I
21 heard, and maybe I just am tired, as we all are, and didn't
22 understand, but I heard the definition of the word
23 "interpretation" being very narrow, to the point where I
24 became concerned that if we taught anything about the status
25 of the literature, keeping in mind that what you have heard

1 for two days is that these devices measure certain
2 physiologic parameters, and those parameters in the
3 literature do have some significance, but certainly in no
4 way have been identified or claimed by any responsible
5 clinician, and certainly not by this manufacturer, to be
6 independently diagnostic. To have diagnostic relevance,
7 absolutely, based upon what's in the literature.

8 So I didn't mean to use our time, Dr. Alpert, to
9 get into some finite discussion, some help, some guidance
10 with respect to what our labeling could be. That wasn't the
11 issue. The issue is the word "interpretation," as it has
12 been applied in the minds of this Panel is absolutely
13 critical with respect to what is a class I device. That's
14 when I raised the issue of what does the Panel mean by the
15 word "interpret."

16 And that was the issue that I was trying to
17 clarify, not some finite hand-holding about what we could
18 say and couldn't say in detail, but rather what does the
19 Panel mean when it draws this distinction? You have a class
20 I device, Mr. Jankelson, but if you do this, you are outside
21 of that classification, and I think that's appropriate, but
22 I am not sure. Maybe I'm just suddenly slow here and not
23 grasping what the Panel means in its classification.

24 Maybe the Chair could summarize. I don't mean to
25 put that burden on you, but--or if somebody just wants to

1 tell me to sit down, I'm not making sense, I'll do that,
2 too.

3 MR. SCOTT: At this point, I can ask the Chair
4 and/or any other Panel members to actually provide
5 suggestions as to a definition for interpretation.

6 CHAIRPERSON JANOSKY: I think earlier Dr. Gutman
7 actually had provided us a very good interpretation, a
8 definition of interpretation, if you wouldn't mind restating
9 that again.

10 DR. GUTMAN: Well, again, you have to realize it's
11 coming from a different product line, but our interpretation
12 would be when you actually took an analytical signal and
13 made it into some clinical end point, not an outcome, but an
14 end point. So if you said you have 17 centimeters and to
15 report out 17 centimeters, well, I assume your instrument is
16 doing that. That's the analytical heart and soul of the
17 instrument.

18 When you convert that into a clinical end point,
19 either a disease end point or a clinical condition, and you
20 are implying that 85 percent or 92 percent or 100 percent of
21 the time it's identifying that, again, from my universe that
22 would be a specific claim that would--I don't know if it'll
23 go to a class II or a class III or something else--it would
24 go beyond the spirit of a general-use instrument. For an
25 immunohistochemical

1 stain it's okay to say the leukocyte common antigen is
2 positive. You can't say a diagnosis lymphoma. You have to
3 put that with four other things, and the keratin is
4 negative, and the mucicarmine is negative, and it's coming
5 from a lymph node, and you put all of the other information
6 together, and that tips you over to calling it a lymphoma,
7 not the leukocyte common antigen.

8 So 17 centimeters shouldn't give you a diagnosis.
9 It should give you a signal, and you put that together with
10 other signals, with the age of the patient, the sex, the
11 history, the physical exam, and you put that all together,
12 and you know how to proceed. If you use that alone, then
13 you have crossed the line, at least the way I interpret this
14 classification.

15 MR. ROLAND JANKELSON: Is the word "independently
16 diagnostic" operative here? I mean, that's what I hear you
17 saying.

18 DR. GUTMAN: Moving from an adjunctive to an
19 independent diagnostic, yes, that's probably a central
20 feature. I would be happy to work with you or to work with
21 Tim and you to resolve these. I think we are all tired and
22 maybe this is--

23 MR. ROLAND JANKELSON: Yes, we are, and I need to
24 not be taking people's time, but it was the Panel that made
25 the recommendation and clearly defined the classification

1 with this one term, "interpretation."

2 DR. GUTMAN: Well, there's a lot of expertise on
3 this Panel, and if we get into a match, we'd be happy to
4 turn to some of these people and query them.

5 MR. ROLAND JANKELSON: Thank you.

6 DR. ALPERT: I was the one that raised the issue
7 of the independents. So let me take that head on. We
8 talked about three levels. We talked about a product that
9 only provides information, and that is what we just
10 classified. We talked about products where understanding
11 that information in relationship to diseases, where there is
12 an interpretation that this level is frequently associated
13 with, and then there's the ones that's independent. You
14 just do this as screening.

15 Steve talked about them as well when he talked
16 about immunohistochemical stains, those that just are used,
17 as he just said, you need one of these and six other things
18 to say anything because you can have positives and negatives
19 that are associated with other cancers.

20 Then when you talked about whether or not you
21 ought to use that signal to begin to move to a therapeutic
22 modality, that was quite different, and then if you are
23 using the same information as a screening--this bin, that
24 bin--it's even higher. And that's the kind of thing that we
25 were addressing in terms of interpretation. Dr. Gutman is

1 absolutely right. Measurement is a signal. The question of
2 how you use that measurement and what it means, what does 17
3 mean versus 19 is an interpretation. It's outcome. It's
4 developed in the literature. It's in the minds of the
5 users, we hope. It is in their skill set that allows them
6 to allows them to understand what it means and what to do
7 about it, and that is the distinction between the device
8 saying this is what it is and the device saying this is how
9 much it is and for the user to do the absorption of that
10 information, putting it with everything else, and then
11 coming up with a diagnosis.

12 CHAIRPERSON JANOSKY: Would any of the Panel
13 members want to comment on the definition of interpretation?

14 DR. MOSES: I would like one quick comment, and I
15 will probably address it to Dr. Gutman or Dr. Alpert. But
16 it would seem to me that it would be acceptable--this is an
17 opinion, I guess, and not a question. It's a comment. If
18 the interpretation of the scan were something that were
19 cited in the literature, that that would be acceptable to
20 put in the manual. Is that a fair assumption? No.

21 In other words, he's got to teach this. He's got
22 to teach this.

23 DR. ALPERT: Again, there are appropriate uses of
24 the published literature, as I said. Using the published
25 literature at the request, if one of you were to ask, "Is

1 there literature on the use of your device in orthodontics?"
2 they may then give you all of the publications on
3 orthodontics--perfectly appropriate.

4 If they want to say that these six papers support
5 this threshold for determining that an orthodontic patient
6 has a specific problem, that has to come through us because
7 that is labeling it in a claims way. That's the issue.
8 That's exactly the issue we are talking about.

9 The literature keeps--you, yourself, have pointed
10 out the literature keeps changing. The literature keeps
11 learning, we hope, and some of that learning, with data to
12 support the claim they can bring that in to support adding
13 it to their manual, absolutely. That's, in fact, what we
14 expect people to do. Bring the literature in and say, "We
15 want to put this on our label. Is that within, you know,
16 here's the data. Can this be legitimately claimed to
17 establish safety and effectiveness?" That's exactly why we
18 are here.

19 DR. MOSES: And that doesn't change status to
20 class I, class II?

21 DR. ALPERT: It can, but it depends on the issues.
22 That gets into what makes it equivalent and not equivalent,
23 and that depends on the specifics of the information,
24 whether it raises new types of questions of safety and
25 effectiveness, whether it is determined to be within or

1 outside the claim. That's the determination we make based
2 on the specific words and the specific supporting
3 information within the process.

4 DR. MOSES: Okay. But if somebody--

5 DR. ALPERT: So it's an option that they can have,
6 but it doesn't say they can--what it says is manufacturers
7 can't just pick and choose literature they want to use in
8 their label. There is a process that oversees it.

9 DR. MOSES: That sounds reasonable.

10 DR. ALPERT: That's all it says.

11 DR. MOSES: But I just feel that they ought to be
12 able to write a manual that can--

13 DR. ALPERT: The manual is labeling and,
14 therefore, it is part and parcel of what we regulate.

15 DR. MOSES: But if that gentleman there writes a
16 textbook on his opinion on how to use it, that's just fine.

17 DR. ALPERT: It's a textbook, and textbooks are
18 textbooks. They're not ours. We don't regulate textbooks.
19 And, again, we recognize text, we recognize published
20 literature, all of that as being appropriate for the
21 clinical community to rely on, absolutely. Our little piece
22 is what the manufacturer writes in their own things.

23 DR. BURTON: Dr. Alpert, I just have one question,
24 which just is a point of clarification for myself. But are
25 you telling us, then, that if a company--and this is not

1 even just this particular company--has a product which they
2 provide instruction on or they provide a course on, anything
3 that they provide as part of the instruction for that course
4 is considered labeling for that product?

5 DR. ALPERT: That's an interesting question. I
6 can tell you that any manual that they write that is
7 intended to be distributed to the people who use their
8 device is labeling. If they write a manual, a how-to manual
9 to how to use their device, that's labeling.

10 DR. BURTON: Thank you.

11 DR. ALPERT: When it comes to training programs,
12 that gets trickier, and that's one of the things that's on
13 the table with the courts. The Agency proposed, FDA
14 proposed, that all of the information that was used in
15 training programs should be directed at the approved use.
16 It's not labeling. You wouldn't regulate it as labeling,
17 but it would be only those things that support the approved
18 uses, the claims, the labeled claims. The courts disagree
19 with us, and that's going to be resolved in the courts.

20 MS. SCOTT: Dr. Janosky, if I could just kind of,
21 hopefully, wrap this up, draw us back in, bring us to focus.

22

23 I just want the Panel to clarify that in their
24 classification recommendation whether or not the intended
25 use specifically can include claims such as this measurement

1 relates to this condition or specifically, no, that the
2 intended use should not include that type of claim.

3 DR. TALLEY: If I could speak to that, it's my
4 understanding that this Panel agreed that the whole realm of
5 the term "interpretation" was delineated or deleted, excuse
6 me, from both of these recommendations for class I.

7 DR. BURTON: I concur with that.

8 CHAIRPERSON JANOSKY: That was my understanding as
9 to what we did state.

10 MS. SCOTT: Okay. At this point, if there are no
11 other comments, I will turn it back over to Dr. Janosky to
12 wrap it up.

13 CHAIRPERSON JANOSKY: Is there any other issue
14 that we need to consider, Dr. Runner?

15 DR. RUNNER: I know it's late, but I just want
16 briefly, if anyone has any other comments on our grid about
17 any of the other classifications, I would like you to feel
18 free to either make those comments now or maybe you can
19 provide them to us in writing at a later date, so that we
20 can determine if there is any need for any further
21 modification of the proposed classification of other devices
22 on our grid.

23 [No response.]

24 DR. RUNNER: No comment.

25 CHAIRPERSON JANOSKY: No comment at this time.

1 DR. RUNNER: But feel free to contact us if you
2 later become awake again and decide you have some comments.

3 MS. SCOTT: Before we close--Dr. Talley?

4 DR. TALLEY: Are we concluded with our business?

5 MS. SCOTT: Yes.

6 DR. TALLEY: I would just like to make one
7 comment. As a new consultant to this Panel, I would like to
8 compliment the staff and officers of the FDA Centers for
9 Devices and Radiologic Health and, specifically, the Dental
10 Products Panel for their handling of this meeting. They
11 have done an excellent job.

12 Thank you.

13 CHAIRPERSON JANOSKY: I would like to thank the
14 Panel and FDA staff, also.

15 MS. SCOTT: Before we close, I would just like all
16 of the Panel members and consultants to turn in your
17 completed questionnaire sheets and supplemental data sheets
18 for the record.

19 Also, I would like to thank all of the Panel
20 consultants and Panel members for participating in this
21 meeting.

22 I also would like to thank Dr. Janosky for taking
23 up the task of acting as chair for this meeting and doing a
24 wonderful job, and I would like to thank FDA staff.

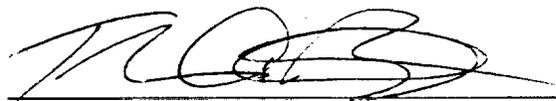
25 CHAIRPERSON JANOSKY: The meeting is adjourned.

1 [Whereupon, at 2:51 p.m., the proceedings were
2 adjourned.]

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C E R T I F I C A T E

I, **THOMAS C. BITSKO**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

A handwritten signature in black ink, appearing to read 'T.C. Bitsko', written over a horizontal line.

THOMAS C. BITSKO