Quickly generate sales in the large US market with medical devices

With Margret Seidenfaden, Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights.

00:00:08 Speaker 1

A podcast by the Jona Institute for medical device manufacturers, authorities and notified bodies.

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Through our consultants, we are seeing how more and more companies are using the U.S.A.

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as the country and the market in which they want to put their products on the market first.

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That is, no longer to Europe.

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This certainly has something to do with these ever-increasing bureaucratic requirements in Europe.

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But anyway, the companies want to do it.

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By the way, our regulatory scientists are already observing this, and that's why the question now is how to create the medical device as quickly as possible, as easily as possible, with little effort

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into this market.

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And that is exactly what I would like to discuss today with Margret Seidenfaden, my colleague.

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Margret, very briefly, because the listeners don't know you yet, imagine what you've done so far, what you're doing at the Johner Institute, so that we can sort it out well.

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Thank you very much, Christian.

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Yes, my name is Margret Seidenfaden.

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I am a medical technology engineer and have a master's degree in business administration.

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I've been working in regulatory affairs for over 10 years now and I've been there

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before my time at the Jona Institute, I worked for various manufacturers.

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Even then, my focus was on regulatory affairs, which means that I supervised international approval, carried it out myself and monitored that it remained valid.

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The U.S.A.

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were of course already an important market at that time.

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I have been at the Jona Institute since 2020 and work there in the Medical Device Team and of course we also focus on the U.S.A.

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work on, for example, strategy development, support in the preparation of submission documents or presubmission requests, or even in terms of the implementation of the Q.

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M.

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requirements.

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Mhm, so exactly the expert we need here, who already X.

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and you are a whole team that takes care of this F.

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D.

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approval.

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So that we can get into it, what are the big steps that a manufacturer should know about that he has to take until finally the product is legal on the market

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is then marketed.

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So, what are the things he needs to do along the way?

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The first step would be to check whether the product is available in the U.

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is also a medical device.

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In 2016, there was a change in the law through the Twenty Four Centures Cures Act, in the course of which the definition of the term medical device was also changed.

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This means that some software products, for example, have been excluded from the scope of the medical device.

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this is important and therefore you should always check whether your own product, although it is a medical device in Europe, is also handled as a medical device in the USA.

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Once I have checked this, the next step would be to look for the product classification.

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The classification works a bit differently in the USA than we know it from Europe.

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We don't have a rule-based system, but a system based on legal requirements.

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The FDA has developed various product groups for this purpose,

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Groups, so-called Regulation Numbers, and in these Regulation Numbers I can then identify the correct product code for my respective product.

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If I have this, this correct product code, then I can also use it to find out what my requirements are.

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That would be the next step.

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This means that I do my classification and then check which requirements apply to my product based on this classification.

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When I have identified this requirement,

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Of course, I can then implement them.

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This includes, for example, the basic general controls that apply to all medical devices, plus possibly other additional requirements.

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This includes that I need an establishment registration.

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As a non-U.S. manufacturer, I always need a U.S.

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Agent.

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I also always have to do a product listing, for example.

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And for most products I also need a Q.M.

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System according to Part 820.

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Wow, that's a lot.

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So, I'll summarize again, as the first to find out, do we have a medical device at all?

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If so, look in this database, yes, what is the product code?

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Because when we have that in turn, we know the class, we know the requirements that have to be met.

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Then you will actually meet this requirement after you have identified it.

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And when you've done all that, then you said, then we'll get to the topic.

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Registration and listing and when all that is done, then you are allowed to enter the market.

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O.K., now maybe let's zoom one level deeper.

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Namely, to these requirements.

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Yes, there was also Q.M., you just mentioned.

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What procedures, I don't even know whether the term approval procedure is the right one, are there?

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Could you give us an overview then?

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Perhaps also say right away, when is such a procedure suitable, how long does it take and what costs are associated with it?

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Yes, the procedure I have to choose.

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is based on the classification for my product.

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I have for products with a low risk, which are usually class 1 and a few class 2 products, which are Exempt, Five ten K.

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Exempt, sometimes G.

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M.

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Exempt, they just have to be listed.

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This means that I do my establishment registration, can then do the listing and can then sell the products directly.

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Do you have an example of such a low-class product?

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One example is hospital beds, for example.

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K.,

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And for the higher-class teams?

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For products usually for Class 2 products, then the Five Ten K would be.

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Procedures or Primark Notifications procedures apply.

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This usually takes 4 to 5 months, I should plan until the F.D.A.

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was examined.

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The costs for this are now almost $22000 or for a small business, then a quarter of that.

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The 510K process is based on the fact that I already have a comparable product in the US market.

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If I now have a new product for which I don't have a comparable product, then I would use the Denovo process.

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This allows me to request a classification into Class 1 or 2 from the FDA for products that do not yet exist.

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that takes a little longer, then the F.D.A.

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A target time of 180 days for the exam.

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But I should definitely plan 9 to 12 months until my product is available on the market.

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The cost of this is now $145,000, or a quarter of that for a small business.

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For high-risk products, i.e. class 3 products, i.e. life-sustaining products, for example,

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They then have to pass the P.M.A.

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procedure, the premarket approval procedure.

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In any case, I have to reckon with a year and the costs are already relatively high at just under half a 1000000.

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Wow, OK, now we have an overview.

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I think most people probably hope that they are exempt and if it doesn't work, that they can get a Five Ten K.

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approval.

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Tell me how it works and so, how do you find out or

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you send the documents there right away if you think it's Five Ten K.

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or what would be your recommendation to try this Five Ten K.

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procedures as smoothly as possible.

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So in the first step, of course, I should check whether the Five Ten K.

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method is actually the method of choice for me, i.e. whether this is the correct one for my product type.

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If I'm undecided, there are always possibilities with the F.

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get in touch.

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We always recommend this because we have had very good experiences with it.

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So I can make an official classification request, for example.

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A 513 G.

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if you call it, then you can get to the F.D.A.

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whether my product falls into this classification.

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When I then identified that the Five ten K.

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procedure is permissible, then in the first step I would first look, O.K., what documents do I have to submit at all, what does the F.D.A. expect.

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from me.

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There is from the F.D.A.

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also fortunately a lot

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Information: For example, there is a Guidance Document, which is called Electronic Submission Template.

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for Medical Device, Five Ten K.

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Submissions, which then state in detail what I need.

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And the Five Ten K.

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The process is based on the fact that I compare myself with a predecessor product, a so-called predicate device.

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And I spend in my Five Ten K.

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procedure to prove that my product is at least as safe and as effective as the product already on the market.

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In other words, a focus or a document, which I always do in addition for ,n Five Ten K.

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is

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this Predicate Device comparison.

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Mhm, ah, that's a good point.

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So, you said, in addition, that resonates a bit now, perhaps compared to the approval Europe, as if we want to call it approval.

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So, if you had a product that would have been class 2 A, 2 B in Europe, now in class maybe also in Europe, you would have already placed it on the market in Europe.

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What additional documentation would you have to create here now?

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Home now the just mentioned product comparison or does it essentially match?

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Many of the documents that the F.D.A.

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are also documents that I now create as part of my normal development, i.e. those that come from my development process, the M.D.R.

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conform.

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That means I can already take on a lot.

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Nevertheless, I should check what the F.D.A.

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for example, special requirements for the product description.

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that I already had the relevant information there.

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The Predicate Device comparison is very important.

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Otherwise, however, it is relatively congruent.

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What is different is the submission format.

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So I now have to submit the Five Ten K fully electronically via the iStar template.

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This means that I have to extract the information from my technical documentation and transfer it to the ISTA template.

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And of course it may be that I don't copy the documents 1 to 1, as I have now created them for the notified body, but that I can copy the information for the F.D.A.

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explicitly.

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Because I want to give the F.D.A.

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only provide what she actually wants to see and no more.

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Mhm, but that's very exciting, because that's what we're now doing in the digital transformation and with the Fit for Future program with the other

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, namely to save exactly this copying, selecting, reformatting, because these are all actually approaches of the, I'll call it, of the 80s to work document-based, whereby yes, and I think that's great, also with this E-Star program, we are already slowly feeling the shift, driven by documents to data and they want to continue on this path.

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That's why, if they come back to the World Medical Device Summit, we have exactly these steps to take

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To discuss, i.e. what I would like to share here, is the good news.

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A lot of this diligent work, namely that, as you just described, the restructuring, recompiling of information into the new target format.

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These are all tasks that will be eliminated in the future, because a computer can do that well.

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So, allow me to make this short interjection.

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But what you said was essentially the same information that we have, yes times from this

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special predicate topic, but in a different structure, other formats, as they are to be submitted.

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Yes, I think this gives us a first overview.

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It works very often that we, or almost in most of the cases that we help to supervise, have such a fifth th K.

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approval.

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This means that there is a Predicate Device.

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What would you do if you can‘t find it?

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That is, if there is no equivalent product to compare yourself with.

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If there is no comparable product and I am not a high-risk product that has a P.M.A.

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procedure, then the procedure of choice is the Denovo procedure.

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However, it is always advisable to contact the F.D.A.

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On the one hand, because the costs for the Denovo process are of course already relatively high and on the other hand, because the amount of work on the part of the manufacturer is of course also high to create the corresponding documentation.

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That is, in the first step I would

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talk to the FDA, you can always contact them again and ask if they know of a comparable product.

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They would then also go looking again.

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Then it is quite possible that the FDA will identify another comparable product.

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If there is indeed no comparable product, then the Denovo process would prove that the product is safe and effective on its own and is ready for its intended use.

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What else would be clarified in these talks?

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Well, you once said, there is certainly no Predicate Device.

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So that you make sure that again, so to speak, not that the F.D.A.

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Say, no, you can use that.

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What other topics would be discussed at these meetings with the F.D.A.

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in order to be on the safe side afterwards and also to have a high probability that this de novo procedure will be successful.

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Yes, so if you work with the F.D.A.

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has clarified that the De Novo procedure is the method of choice,

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then the next step would be to discuss which documents the F.D.A.

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for that specific product, including what tests to do, what standards to follow, whether I need clinical trials, and so on.

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You should clarify all this in advance in order to be sure that you have everything when you have submitted the documents.

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Because if the F.D.A.

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gaps, then you only have 180 days to respond.

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And that can be difficult under certain circumstances if you have to catch up on tests or a clinical study, you can't do that in time.

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Then you would have to resubmit it, that would be just annoying.

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K., so it's already clearer what actually distinguishes such a de novo procedure.

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You also emphasized again how important these preliminary clarifications are, yes, in these presubmission meetings.

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In which of these steps do you support the manufacturers?

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We actually support the

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the entire process.

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So even when the product is still in development, you start developing your regulatory strategy.

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That is, we already start to support and see, O.

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K., in which class does the product belong, let's see, are there predicate devices, which would be the appropriate submission way, are there any open questions that can be answered with the F.

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So these presubmission meetings, we always like to recommend this to our customers,

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because they are really helpful.

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So you get a well-founded good answer from the FDA within a manageable period of time, with which you can then continue to work.

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This means that the FDA can provide input on the regulatory requirements as early as the development stage.

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Exactly, when the development is completed, we are of course also happy to support you with the preparation of the submission documents, further communication with the authorities, the sending of the

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from the documents, i.e. actually the entire process until the product is on the market.

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Yes, that's great.

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We also link the information where you can support exactly, so that you can listen to it again.

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We also link the website to this approval procedure as a whole, then you can also follow up on it.

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Reading, yes, if you look at it and if you maybe come back to the introduction, you can almost be a little envious of the U.S.A.

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On the one hand, you can now get into the market there faster.

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On the other hand, as you just described, you also have support from the authorities, yes, they give you

advice.

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Whereas the notified bodies always have to say: ‚Yes, we are not allowed to advise.‘ Well, you can be a little jealous.

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But the good news is that the U.S.A.

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exists.

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This is also a very attractive market and you have just described that you are helping with all these steps.

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So, if you are interested, just get in touch.

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Margret, thank you very much for these insights.