P910066/S11

SPINALOGIC™ BONE GROWTH STIMULATOR
Summary of Safety and Effectiveness

I. General Information

Device Generic Name:	Noninvasive Bone Growth Stimulator
Trade Name:	SpinaLogic™
Applicant's Name and Address:	OrthoLogic 1275 W. Washington Street Tempe, AZ 85281
Premarket Approval (PMA) Application: Supplement Number:	P910066 S11
Date of Notice of Approval to Applicant:	DEC 17 1999

II. Device Description

The SpinaLogic™ is a portable, battery-powered, microcontrolled, noninvasive bone growth stimulator. It incorporates the same technological features as OrthoLogic's OrthoLogic™ Bone Growth Stimulator (P910066, approved March 4, 1994).

III. Indications for Use

The SpinaLogic is a noninvasive electromagnetic bone growth stimulator indicated as an adjunct treatment to primary lumbar spinal fusion surgery for one or two levels.

IV. Contraindications

- Demand-type pacemaker and implantable cardiovertor defibrillator (ICD) operation may be adversely affected by exposure to combined static and dynamic magnetic fields. Physicians should not prescribe the SpinaLogic™ for patients with such devices.

- The safety and effectiveness of the SpinaLogic™ in pregnant women have not been studied, and the effects of the device on the mother or the developing fetus are unknown, thus, this device should not be used in pregnant women. If a woman becomes pregnant during treatment with the SpinaLogic,™ treatment should be discontinued immediately.

V. Precautions

- The safety and effectiveness of the SpinaLogic™ has only been studied in those patients having spinal fusion treatment. The safety and effectiveness of this device in patients receiving instrumentation, which may distort the magnetic field generated by the device and thus produce less effective treatment, has not been established.

- The safety and effectiveness of the use of this device on individuals lacking skeletal maturity has not been established.

- The safety and effectiveness of this device in treating patients with the following conditions has not been established and therefore the safety and effectiveness of the device in these individuals is unknown: osseous or ligamentous spinal trauma, spondylitis, Paget's disease, severe osteoporosis, metastatic cancer, renal disease, and uncontrolled diabetes mellitus.
- Animal studies conducted to date do not suggest any long term adverse effects from use of this device. However, long term effects in humans are unknown.
- Compliance with the treatment schedule, timely battery change and proper care of the device are essential. The device will not perform properly and treatment may be unnecessarily prolonged if the patient fails to adhere to the care routine.
- This device should not be used if there are mental or physical conditions which preclude patient compliance with the physician and device instructions.
- The SpinaLogic™ Bone Growth Stimulator was tested for electromagnetic compatibility and was found to comply with the limits for medical devices specified in IEC 601-1-2:1993. These limits are designed to provide reasonable protection against harmful interference in a typical medical or household setting. However, if the SpinaLogic™ Bone Growth Stimulator should appear to affect or be affected by other devices in the vicinity, please try to correct the interference by one or more of the following measures:
  - increase the separation between the SpinaLogic™ and other electrical equipment or magnetic (metal) structures or
  - call the local OrthoLogic Representative or Customer Service
- It is not recommended that the SpinaLogic™ be used while smoking or near excessive heat or an open flame.
- The following factors will be essential in allowing the SpinaLogic™ to be most effective in achieving a successful spinal fusion:
  - compliance with physician instructions
  - compliance with daily treatment schedule
  - proper care of the device
- Components in this system are to be used only with OrthoLogic components. No attempt should be made to modify or repair this device.

VI. Alternate Practices and Procedures

Alternatives to use of the SpinaLogic™ include physical therapy, medications, external bracing, chiropractic care, exercising, and spinal fusion therapy (with or without instrumentation) and with or without concomitant stimulation. Other stimulation devices are in commercial distribution and are indicated for "use as an adjunct electrical treatment to primary spine fusion surgery." These other devices utilize different methods to stimulate bone growth and consist of both invasive and noninvasive stimulators.

VII. Marketing History

The SpinaLogic™ has neither been marketed nor commercially distributed inside or outside the United States.

VIII. Potential Adverse Effects of the Device On Health

No adverse reactions or medical complications related to the use of this device were reported during the clinical investigation.

IX. Summary of Non-clinical Studies

The SpinaLogic™ incorporates the same technological features of the OrthoLogic™ Bone Growth Stimulator (P910066, approved March 4, 1994) and the treatment signal for the SpinaLogic™ is identical to that of the OrthoLogic™. A series of laboratory studies were previously conducted in support of the safety and effectiveness of the OrthoLogic™ Bone Growth Stimulator and reported in P910066, Volume 3, Section 5.0, pages 2-69). Toxicological studies on isolated cells, as well as animals, were performed to evaluate the safety of combined static and dynamic magnetic fields. Further, *in vitro* and *in vivo* studies were conducted to determine whether the application of these magnetic fields in animal models would stimulate bone healing and other related biological responses. Many of theses previous laboratory experiments included whole body exposure to the test animals (and thus included vertebrae and nerve tissue). Additional details of the pre-clinical studies gathered using the OrthoLogic™ can be found in the Summary of Safety and Effectiveness for OrthoLogic™ Bone Growth Stimulator (P910066).

X. Summary of Clinical Investigation

Clinical data to support the safety and effectiveness of the SpinaLogic™ were collected as part of multi-center trial.

A. Study Design

The clinical study was a prospective, randomized, double-masked, placebo-controlled trial where the placebo appeared to be a fully functioning SpinaLogic™, however no therapeutic treatment signal was delivered. The purpose of this clinical study was to investigate the safety and effectiveness of the SpinaLogic™ as an adjunct to spinal fusion.

The endpoint for the determination of effectiveness was the status of the fusion after 9 months of treatment as judged by a panel of evaluators. The panel was comprised of the investigator (treating orthopedic surgeon) and two masked reviewers: a musculoskeletal radiologist and an orthopedic surgeon. Safety was determined by evaluating all reports of device-related complications and adverse effects.

The study was designed to eliminate potential bias. As previously noted, the placebo device appeared to the patient and his/her attending surgeon as a fully functioning device, but it did not provide therapy. The low energy magnetic fields utilized during active treatment could not be sensed by the surgeon or the patient, and therefore, allowed the masked randomization of active and placebo (inactive) stimulators. The assignment of an active or placebo stimulator to patients was block randomized by investigational site and stratified within investigational sites by the number of vertebral levels fused. Lists of randomized treatment assignments were sent to the study sites. Separately within each study site and within strata defined by one or two levels of fusion, each list provided a block size of six so that there was good balance between treatment arms for each multiple of six patients.

The patients were seen at enrollment, three, six and nine months post-surgery for imaging of the fusion site and clinical assessment (current occupational status, physical activity, pain, medication usage, type of immobilization, fusion status, radiographic findings and device usage). Additionally, a 3-month post-treatment follow-up visit was conducted to confirm the findings of the 9-month post-surgery follow-up. Imaging techniques included plain radiographs (anteroposterior (AP), lateral and obliques) and

CT scans. Lateral flexion-extension radiographs were also taken when clinically indicated.

B. Inclusion/Exclusion Criteria

1. Inclusion Criteria

Patients meeting the following inclusion criteria and not specifically excluded (see Exclusion Criteria below) were enrolled in this study:

- Over 18 years of age;
- Having undergone a primary intertransverse fusion without internal fixation of one or two vertebral levels between the third lumbar vertebrae (L3) and the sacrum (S1) within the last 30 days; and
- Grafted with autograft alone or in combination with allograft.

2. Exclusion Criteria

Patients who met any of the following exclusion criteria were not eligible for participation in this study:

- Pregnant women shall not participate in this study, and if a patient became pregnant, she was immediately withdrawn from the study. Additionally, female subjects of childbearing potential should have used an acceptable form of birth control, i.e., birth control pills, diaphragm with spermacidal gel or condom;
- Diagnosed as having metastatic cancer, metabolic bone disease, spondylitis, Paget's disease, moderate to severe osteoporosis, renal dysfunction and uncontrolled diabetes mellitus or having an implanted cardiac pacemaker; and
- Underwent a spinal fusion for vertebral trauma or scoliosis.

C. Enrollment, Treatment and Follow-Up Visits

The device was dispensed within 30 days following fusion surgery. The patient used the SpinaLogic™ for 30 minutes per day according to the instructions in the patient manual. The device was used for nine months following enrollment (the SpinaLogic™ is programmed to cease operation at the end of 270 days).

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D. Outcome Measures

1. Safety

During this clinical investigation all device-related comments, complications and adverse effects were recorded and evaluated.

2. Effectiveness

a. Radiographic Assessment

The status of the fusion was graded into one of four categories, from no fusion (0) to solid fusion (3). When two levels were involved, the lowest grade at either level was utilized for the fusion assessment. For purposes of outcome and as defined in the protocol, the grades of "0" and "1" were combined into a single category, "No Fusion." Grades "2" and "3" were combined into another category, "Fusion".

b. Role of the Assessment Panel in Fusion Determination

The outcome was a combination of the rating assigned by the investigator (masked treating orthopedic surgeon) and two independent masked reviewers: a musculoskeletal radiologist and an orthopedic surgeon. When the radiologist and the investigator agreed, the fusion was assigned their agreed-upon status. When the investigator and radiologist disagreed, the masked orthopedic surgeon's rating was used as a tiebreaker.

Panel decisions were made in two manners:

i. Original Panel

- Treating Surgeon – The Treating Surgeon, had access to all radiographic imaging, clinical, and surgical information.

- Radiologist – Radiologist utilized only the radiographic imaging information, as stated in the original investigational protocol.

- Independent Surgeon – The Independent Surgeon, utilized only radiographic imaging information to make the fusion assessment, as stated in the original investigational protocol.

ii. Secondary Panel

In an effort to provide an analysis which allows the independent surgeon the opportunity to review a patient's clinical background prior to making a determination of the patient's fusion status, a secondary panel analysis was performed. This secondary analysis is in the spirit of FDA guidance which historically recognize the importance for clinical patient information to be included in the radiographic evaluation of fusion.

In the Secondary Panel Assessment the only reviewer to do an additional review was the Independent Orthopaedic Surgeon (the Treating Surgeon's and the Radiologist's assessment from the Original Panel were utilized in the Secondary Panel Assessment).

The Independent Surgeon did an additional review in the Secondary Panel Assessment and was provided additional information when compared to his original review. Specifically, in the Secondary Panel Assessment the Independent Surgeon utilized all radiographic imaging, as well as the clinical, and surgical information. Specifically, he had the Enrollment form, Follow-up forms and operative record.

The enrollment form included patient demographic data, medical history, prior spinal treatments, diagnosis, physical activity and baseline pain.

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The follow-up forms included the patients assessment of physical activity, current pain, pain medication usage, current immobilization and device usage. The Treating Surgeons' radiographic findings were masked on all follow-up forms. He had no attending surgeons' notes, opinions or findings that would have made known to him the Treating Surgeons' findings.

The operative report included specific information on what surgical procedure was performed, the amount, type and source of bone graft utilized.

As with his previous review the Independent Surgeon was masked as to the active or placebo status of the patient. He was also masked to his original assessment. He was masked as to the Radiologist's and Treating Surgeons' assessment as well as being masked to the outcome of the original panel."

E. Study Endpoint

The study endpoint was assessment of the fusion after 9 months of treatment as judged by a panel of three evaluators.

F. Subject Population : Enrollment and Withdrawal

The first patient was enrolled in this study on Feb 17, 1993. At the time of database closure, July 13, 1998, there were 243 patients who theoretically should have completed the 3-month post treatment follow-up visit. This defines the intent-to-treat population.

Two-hundred and one (201) patients make up the evaluable population which includes all patients who completed their 9- month follow-up visit within 28 days of the prescribed date of the follow-up and their 3-month post–treatment follow-up visit within a window of –28 and +90 days around the prescribed date of the follow-up.

Of the 243 patients, 201 patients were evaluable. Eight (8) placebo and 8 active patients voluntarily withdrew before the 9-month visit, 5 placebo and 5 active patients were withdrawn by their physician before the 9-month visit, 1 placebo and 1 active patient died prior to their 9-month visit, 2 placebo patients were withdrawn due to protocol violations, and 5 placebo and 7 active patients were withdrawn because they had follow-up visits outside of the plus-or-minus 28 day window. These patients are evaluated in the Intent-To-Treat analysis but excluded from the evaluable patient analysis.

All patients are accounted for in this study. Patient adherence with the 3, 6 and 9 month follow-up visit requirement was greater than 94%.

G. Treatment Compliance

For the majority of both active and placebo patients treatment compliance was greater than 75% compliance for at least 85% of the placebo treated patients and 75% of the active treated patients.

H. Demographic and Medical and Socioeconomic Characteristics

Demographic, medical and socioeconomic characteristics of the entire patient population are provided in the table below. Some data for one active case (*) is not shown because of incomplete records for the case. These data were compared and tested for statistical differences between the placebo and active patient populations.

Demographic, Medical and Socioeconomic Characteristics

Demographics		Placebo	Active	Test: P-value
Age, yr.(Calculated)	N	118	124*	T(240):
	Mean	56.58	56.77	0.92
	Std	15.03	15.47	
	Median	57.00	57.00	
	Min	26.00	22.00	
	Max	82.00	87.00	
Sex	Male	43(36%)	51(41%)	Exact:
	Female	75(64%)	74(59%)	0.51
Height, in.	N	118	124	T(240):
	Mean	66.67	66.26	0.44
	Std	4.02	4.19	
	Median	66.00	65.00	
	Min	57.00	60.00	
	Max	76.00	76.00	
Weight, lb.	N	118	124	T(240.0):
	Mean	171.47	176.98	0.25
	Std	35.25	38.58	
	Median	170.00	177.00	
	Min	105.00	95.00	
	Max	285.00	279.00	
Medical & Socioeconomic Baselines				
Currently Smoke	No	104(88%)	10584%)	Exact:
	Yes	14(12%)	19(15%)	0.46
Prior Discectomy	No	92(78%)	100(80%)	Exact:
	Yes	26(22%)	24(19%)	0.64
Prior Laminotomy	No	94(80%)	95(76%)	Exact:
	Yes	24(20%)	29(23%)	0.64
Current Occupation	Not Employed	47(40%)	55(44%)	CMH(1):
	Unable to Work	40(34%)	36(29%)	0.96
	Sedentary	9(8%)	8(6%)	
	Light Labor	10(8%)	11(9%)	
	Moderate Labor	7(6%)	8(6%)	
	Heavy Labor	5(4%)	6(5%)	
Current Activity	Minimal	76(64%)	84(67%)	CMH(1):
	Light	19(16%)	17(14%)	0.65
	Moderate	16(14%)	17(14%)	
	Active	7(6%)	6(5%)	
Back Pain	None	6(5%)	4(3%)	CMH(1):
	Mild	12(10%)	17(14%)	0.67
	Moderate	21(18%)	26(21%)	
	Severe	79(67%)	77(62%)	
Leg Pain	None	5(4%)	8(6%)	CMH(1):
	Mild	6(5%)	14(11%)	0.29

	Moderate Severe	24(20%) 83(70%)	16(13%) 86(69%)	
Current Surgery				
Levels Fused	One Two	83(70%) 35(30%)	83(66%) 41(33%)	Exact: 0.58
Autogenous Graft	Cancellous Corticocancellous Both	18(15%) 36(31%) 64(54%)	18(14%) 41(33%) 65(52%)	Chi sq (2): 0.91
Allograft	No Yes	93(79%) 25(21%)	98(78%) 26(21%)	Exact: 1.00

The statistical test results demonstrate that the randomized assignments of patients to the two treatment arms resulted in a very well balanced distribution of patient characteristics between placebo and active devices. No statistically significant differences were found for the clinical variables cited.

I. Results

Data were analyzed using SAS 6.12 and EGRET software. Fishers Exact tests and Student t-tests were used to examine the relation of individual risk factors to the outcome. As defined in the statistical section of the study protocol, the analysis began with an examination of simple cross-tabulations, separately stratified tables of treatment outcome at nine months after study entry, by gender and by number of levels fused. To further examine the finding demonstrated by the simple cross-tabulations, an analysis using logistic regressions was then performed, allowing for the adjustment of several covariates in the same model, which allowed the relative contribution of terms to be assessed. The two methods complement one another, presenting a more complete picture of the relation of treatment to outcome than is available with either analysis alone. All statistical tests were two-sided and a p-value of 0.05 was considered significant.

1. Study Endpoint (9-Months)

Percent Fusion Success as Determined by the Original Panel as proposed within the Investigational Protocol is as follows:

Percent Fusion Success as Determined by the Original Panel at 9 months

	Placebo	Active	P-Value
All Patients	43 (44%)	54 (52%)	0.324
Males Only	22 (55%)	16 (39%)	0.184
Females Only	21 (37%)	38 (60%)	0.011

This data demonstrates a trend towards a positive effect as an adjunctive treatment in the total patient population and the female population, however, there is a trend towards a negative effect in the male population. Additionally, the data demonstrates that this treatment effect is only statistically significant in the female population.

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In an effort to provide an analysis which allows the independent surgeon the opportunity to review a patient's clinical background prior to making a determination of the patient's

fusion status, a secondary panel analysis (described above in X.D.2.a.ii) was performed. This secondary analysis is in the spirit of FDA guidance which historically recognize the importance for clinical patient information to be included in the radiographic evaluation of fusion. Provided below is a summary of Fusion Success as determined by the Secondary Panel.

Percent Fusion Success as Determined by the Secondary Panel at 9 months:

	Placebo	**Active**	**P-Value**
All Patients	**42 (43%)**	67 (64%)	0.003
Males Only	22 (55%)	25 (61%)	0.656
Females Only	20 (35%)	42 (67%)	0.001

In this instance, the data demonstrate a trend towards a positive effect as an adjunctive treatment in the overall, male and female populations. The data also demonstrates that this treatment effect is statistically significant in the overall population and in women (p-values < 0.05), while the treatment is not statistically significant in the male population.

Provided below is a gender breakdown, by active or placebo status, of those patients whose status changed during the Secondary Panel evaluation.

Comparison of Independent Surgeons Findings – Male Patients

	Not Fused -> Fused	Fused -> Not Fused	No Change
Active	11	1	29
Placebo	6	4	30
Total	**17**	**5**	**59**

Comparison of Independent Surgeons Findings – Female Patients

	Not Fused -> Fused	Fused -> Not Fused	No Change
Active	10	6	47
Placebo	6	11	40
Total	**16**	**17**	**87**

Seventeen (17) men's status' changed from "Not Fused" to "Fused" while 5 had a status change of "Fused" to "Not Fused." Sixteen (16) women's status' changed from "Not Fused" to "Fused" while an almost equal number (17) had a status change of "Fused" to "Not Fused

Although not originally proposed, the secondary analysis is a separate analysis of the data which incorporates clinical and radiographic evaluation of patients is in accordance with FDA DRAFT GUIDANCE (Released for comment on: March 18, 1998): which states: *"Success should be demonstrated in terms of both radiographic and clinical healing."* The original analysis did not take allow each reviewer to independently assess both clinical and radiographic conditions of each patient.

Thus, even though the method of data collection utilized by the Secondary Panel was not prescribed within the Investigational Protocol, the merits of this methodology support its use.

2. Three Month Post-Treatment Follow-up

A 3-month post-treatment follow-up visit was conducted to confirm the findings of the study endpoint (9 months post surgery follow-up).

One hundred eighty eight (188) of the 201 patients evaluated at 9 months were evaluable at the 3-month post-treatment follow-up visit. Ninety-one (91) placebo cases and 97 active cases.

Provided in the table below is the accountability of patients between the 9-month and 3-month post-treatment follow-up visits.

Accountability of Patients: Between 9-month and 3-month Post-treatment Follow-up Visits

	Placebo	Active	Total
Evaluable @ 9-month visit	97	104	201
Patient voluntarily withdrew after 9-month visit	0	1	1
Patient was withdrawn by physician after the 9-month visit	0	2	2
Visit out of window	1	3	4
Not assessable radiographs or CT scans	5	1	6
3-month post-treatment evaluable population	91	97	188

Provided in the table below are the results for the 3-month post-treatment follow-up visit for all patients.

3-month Post-treatment Follow-up (All Patients)

Device	No Fusion		Fusion		Total
	Count	Row %	Count	Row %	
Placebo	48	53%	43	47%	91
Active	36	37%	61	63%	97
	84		104		188
P-value (Fisher's Exact Test)	.040				
Odds Ratio (C.I.)	1.891(1.058-3.383)				

At the 9-month follow-up visit 43% and 64% of placebo and active-treatment patients, respectively, had fused (n=201, p=0.003, Fisher's exact test). At three months post treatment, these outcomes had only changed slightly 47% and 63% in the placebo and active-treatment groups, respectively. At three months post treatment there was still a positive treatment effect (p = 0.040). Provided in following table are displayed the agreements and disagreements in outcomes at the study endpoint (9-month) and 3-month post-treatment follow-up visits.

Outcome Confirmation: 9 months to 3 months post-treatment

Fusion Status	3-months post-treatment	
9-Month Visit	No Fusion	Fusion
No Fusion	80	5
Fusion	4	99

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One hundred and seventy nine (179) of the 188 patients (95%) of the patients were the same fusion status, fused or not fused, at 3-months post- treatment as they were at 9-months and 5 patients (3%) progressed from not fused to fused. The remaining 4 patients (2%) considered fused at 9-months were not fused at 3-months post- treatment.

Therefore, the findings at the 3-month post-treatment follow-up visit are consistent with and confirm those seen at the study endpoint (9-month follow-up visit).

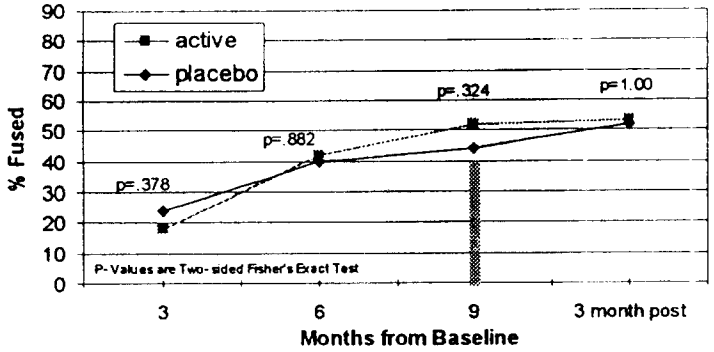
3. Longitudinal Analysis:

The original panel analysis shows that, for all patients and male patients there is no statistically significant difference between the active and placebo groups at any timepoint. For the female patients, there is a statistical significance between the active and placebo groups *only* at the 9 month (study endpoint) timepoint.

The secondary panel analysis shows there is a statistically significant difference for between the active and placebo groups *only* at the 9 month (study endpoint) timepoint for the overall patient population. For the male population, there is no statistically significant difference between the active and placebo groups at any time point. For the female population, there is a statistically significant difference between the active and placebo groups at the 6-month, 9-month (study endpoint) and 12-month (3 month post-treatment) timepoints.

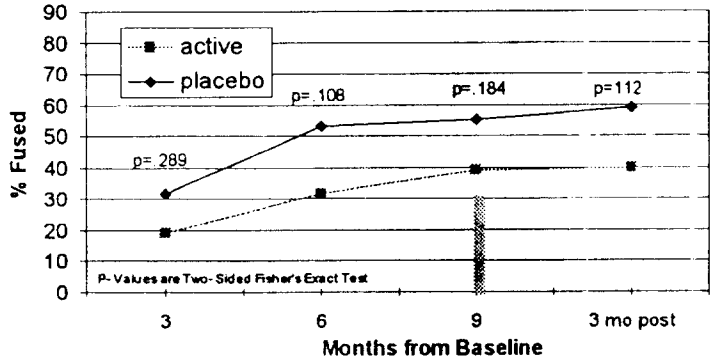
Original Panel Assessment

Fusion by Visit - All Patients (N=201)



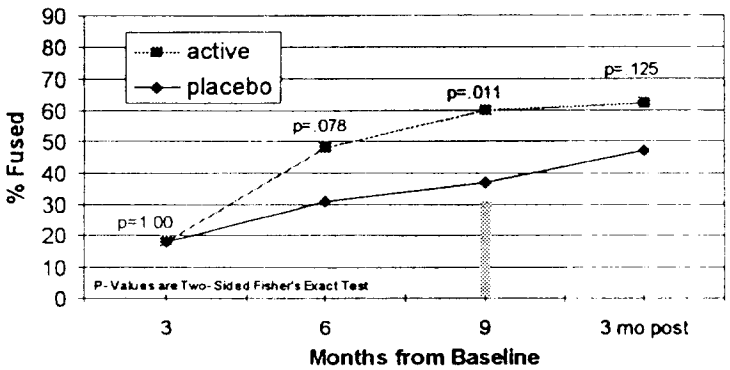
Original Panel Assessment

Fusion by Visit - Male Patients (N=81)



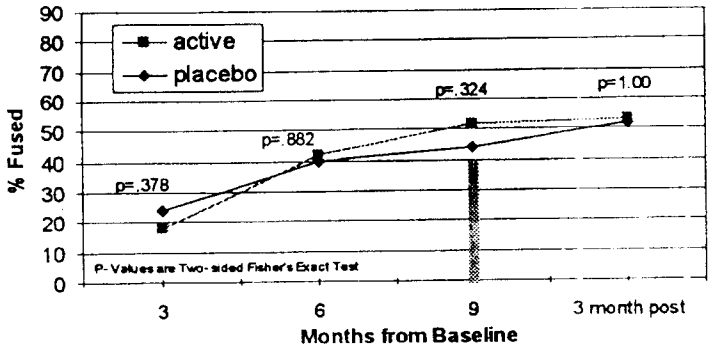
Original Panel Assessment

Fusion by Visit - Female Patients (N=120)



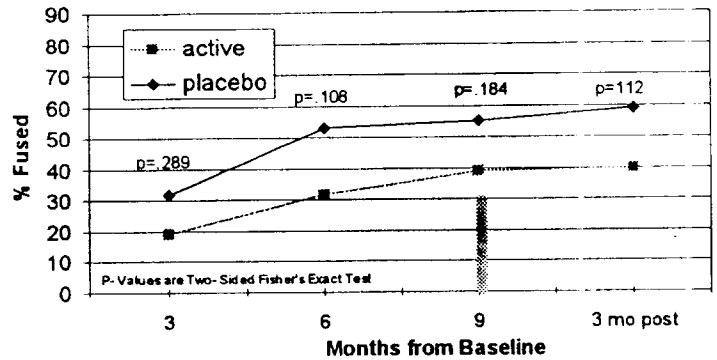
Original Panel Assessment

Fusion by Visit - All Patients (N=201)



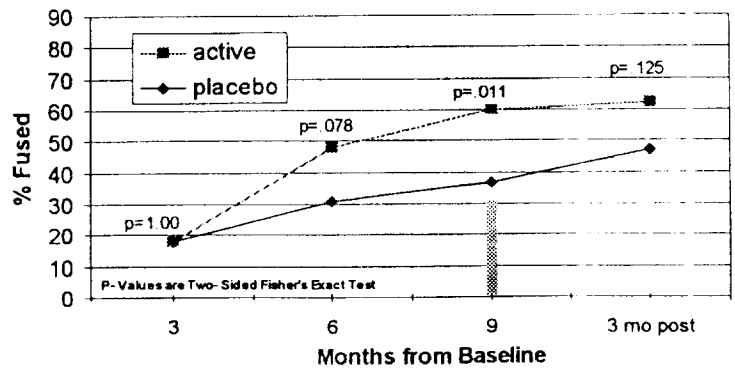
Original Panel Assessment

Fusion by Visit - Male Patients (N=81)



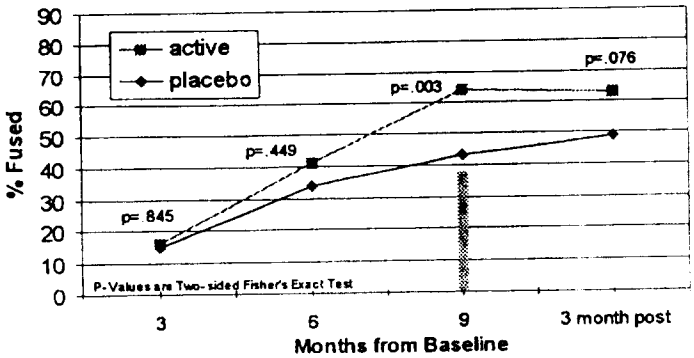
Original Panel Assessment

Fusion by Visit - Female Patients (N=120)



Secondary Assessment

Fusion by Visit - All Patients (N=201)



Secondary Assessment

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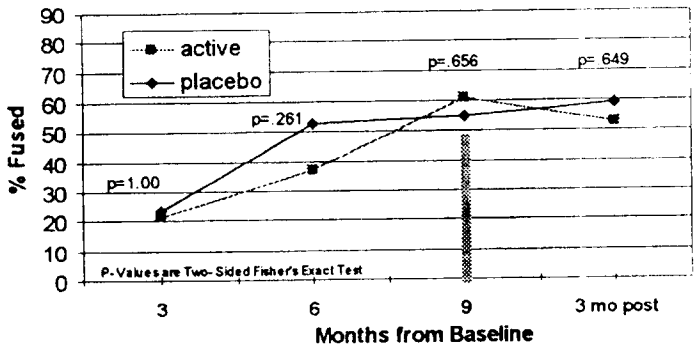

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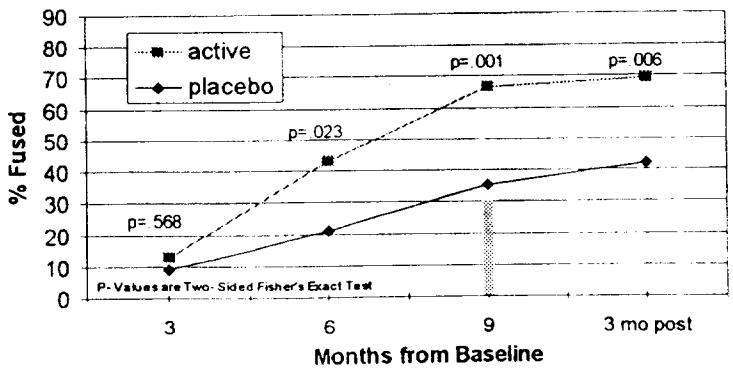

4. Logistic Regression

To further examine the treatment effect, an analysis using logistic regression was performed. This approach allows for the adjustment of covariates that might potentially impact the outcomes in the same model and assess the relative contribution of individual terms. The logistic regression approach complements the tabular approach presented above, presenting a more complete picture of the relation of treatment to outcome than is available with either analysis alone. The analysis examined the data for main effects as well as interactions with treatment.

Several logistic regression models were run to examine aspects of the data. The primary focus of the logistic regressions were the relation of treatment, active versus placebo, and fusion, appropriately dealing with the covariates of gender, smoking status, number of levels fused, and the anatomical site of the levels that were fused. These covariates were chosen because the literature suggests that they are candidates for main effect terms in the logistic regression model. The interaction with treatment was also examined, since the same covariate may appear in both sorts of terms, main effect or interaction.

The logistic regression findings demonstrate that, in distinct models, the only significant main effects are treatment, gender, and current smoking. The only nearly significant interaction is gender by treatment. There are no significant interactions of treatment with current smoking, number of levels fused, or anatomical levels fused. This justifies dealing in a unified manner with the subsamples of patients with one and two levels fused, and also unifying the data for patients with varying anatomical levels.

5. Intent-To-Treat Analysis

An intent-to-treat analysis was performed in order to examine the sensitivity of findings to missing or excluded values. A series of tabular analyses were run to examine 9-month outcomes. When outcomes were missing, in separate analyses, fusion status was imputed as fused, not fused, or assigned its most recent known value (LVCF) as seen at later of 3 or 6 months post-entry. Additionally, patients who had been excluded in previous analyses because their 9-month visit was outside the 28-day compliance window were now included and assigned their observed outcome at the visit recorded on the nine-month visit form. Using each of the three imputation schemes, tabulations were done separately for all subjects, males and females.

Using the data from the Secondary Analysis, there was a statistically significant treatment effect in favor of the active device for all patients: p-values were 0.006, 0.015, and 0.007 for imputation as fused, not fused, and "LVCF". For males, there was no statistically significant treatment effect: p-values were 0.521, 0.684, and 0.838 for imputation as fused, not fused, and "LVCF" For females, there was a statistically significant treatment effect in favor of the active device: p-values were 0.004, 0.0005, and 0.0003 for imputation as fused, not fused, and "LVCF"."

In conclusion, the effectiveness findings cited above for the SpinaLogic™ device are unaffected by several reasonable imputations of missing data in an intent-to-treat analysis.

XI. Conclusions Drawn from the Studies

All of the data provided in the previous sections describing the pre-clinical, clinical studies provide reasonable assurance of the safety and effectiveness of the SpinaLogic™ when

used by trained physicians as a non-invasive bone growth stimulator used as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels.

XII. Panel Recommendations

This is a PMA supplement which did not require panel review.

XIII. CDRH Decision

CDRH recommends approval for the SpinaLogic,™ a noninvasive electromagnetic bone growth stimulator indicated as an adjunct treatment to primary lumbar spinal fusion surgery for one or two levels.

XIV. Approval Specifications

A Post-market Study will not be required for this device. No significant clinical issues of safety and effectiveness remain to be collected which would yield clinically significant information which would necessitate modifications to device indications, adverse events, contra-indications, precautions or warnings.